

Wirral Clinical Commissioning Group

Serious Incident Policy

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Introduction

Introduction

This policy sets out for staff of Wirral Clinical Commissioning Group (CCG) and their relevant local provider organisations how Serious Incidents should be reported, managed and investigated.

The policy has been developed collectively with West Cheshire Clinical Commissioning Group (CCG) East Cheshire Clinical Commissioning Group (CCG), South Cheshire Clinical Commissioning Group (CCG), and Vale Royal Clinical Commissioning Group (CCG) to comply with the 2015 'NHS England Serious Incident Framework: Supporting learning to prevent recurrence'¹ [hereon 'the Revised Framework'] while setting out a locally agreed set of principles to ensure consistency in Serious Incident reporting, management and monitoring across Wirral CCG and Cheshire CCG's. This reflects the Revised Framework's recommendation that commissioners must work collaboratively to agree how best to manage Serious Incidents that occur in their services².

The priority of the Wirral CCG and Cheshire CCGs is to ensure that Serious Incident investigations achieve their fundamental purpose of ensuring that lessons are learnt to prevent similar lessons from re-occurring.

The NHS England Serious Incident Framework 2015

The NHS England national frameworks can be found at the following links:

- [NHS England Serious Incident Framework: Supporting Learning to prevent recurrence](#)
- [NHS England Serious Incident Framework 2015/2016 – Frequently asked questions](#)
- [NHS England Revised Never Events Policy and Framework](#)

The Revised Framework replaces the 'National Framework for Reporting and Learning from Serious Incidents Requiring Investigation' issued by the National Patient Safety Agency (NPSA, March 2010) and NHS England's 'Serious Incident Framework' (March 2013). It also replaces and the 'NPSA Independent investigation of serious patient safety incidents in mental health services, Good Practice Guide' (2008)

The Revised Framework confirms that the fundamental purpose of patient safety investigations is to learn from incidents, and not apportion blame, while endorsing the application of the recognised system-based method for conducting investigations, commonly known as Root Cause Analysis (RCA), and its potential as a powerful mechanism for driving improvement.

¹ Full policy document available at: <http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framwrk-upd.pdf>

² See p.24 of full policy document at: <http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framwrk-upd.pdf>

The Revised Framework made two significant operational changes:

1. Removal of grading – Under the revised framework Serious Incidents are not defined by grade. All incidents meeting the threshold of a serious incident must be investigated and reviewed according to principles set out in the Framework.
2. Timescale – A single timeframe (60 working days) has been agreed for the completion of investigation reports. This will allow providers and commissioners to monitor progress in a more consistent way. This also provides clarity for patients and families in relation to completion dates for investigations.

2. Purpose

The purpose of this policy is to set out a consistent and explicit agreement as to how the principles of the Revised Framework will be applied to the management of Serious Incidents that occur within the regions covered by the Wirral CCG and Cheshire CCGs.

The policy has been written to define the role of the individual Wirral CCG and Cheshire CCGs in managing their provider organisations to improve patient safety through the Serious Incident investigation process. The policy is intended to apply to both in-house and Commissioning Support Unit (CSU) CCG Serious Incident management teams, depending on the CCG's local arrangement.

3. Scope

Section SC 33 of the NHS Standard Contract 2015/2016 confirms that providers must comply with the revised NHS Serious Incident Framework³. This policy is therefore intended to compliment (rather than replace) the incident reporting systems already operating within organisations that provide NHS funded care. The Wirral CCG and Cheshire CCGs do however expect all Organisations commissioned to provide NHS funded healthcare within the region to incorporate the requirements of this policy into their contracting arrangements and own local policies.

The Wirral and Cheshire CCGs would also remind Providers that certain Serious Incidents require interfaces between the Revised Framework and other national guidance as listed below⁴:

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

- [Prisons and Probation Ombudsman: PPO Clinical Reviews Part 1 – Commissioning bodies. September 2014](#)

Serious Case Reviews and Safeguarding Adult Reviews

- [Working Together to Safeguard Children](#)

³ See p.33 of Contract: <http://www.england.nhs.uk/wp-content/uploads/2015/03/14-nhs-contrct-serv-conditions.pdf>

⁴ Full details of this are outlined in Section 1.5 of the Revised Framework available at: <http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framwrk-upd.pdf>

- [Safeguarding Adult Reviews](#)

Domestic Homicide Reviews

- [Domestic Violence, Crime and Victims Act 2004, Section 9 \(3\)](#)
- [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

- [Interim Guidance for Managing Screening Incidents \(2015\)](#)

The Wirral CCG and Cheshire CCGs also emphasise that this policy does not replace the duty of Providers to inform the following interested bodies when the circumstances of a Serious Incident warrant it, as set out below (in accordance with Appendix 2 of the Revised Framework⁵):

- The **National Reporting and Learning System (NRLS)** where the incident is a patient safety incident.
- 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, willfully neglectful or that harm/adverse consequences were intended. Where possible, any Serious Incident investigation should continue alongside criminal proceedings, although this should be discussed with the police. Investigations should only be put on hold in exceptional circumstances following a request from the Police, a Coroner or a Judge.
- 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** 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

⁵ See Appendix 2, pp. 54-60 as set out in the Revised Framework available at: <http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framework-upd.pdf>

- 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
- **Monitor** where a Serious Incident may raise potential concerns over the Provider's compliance with their licence
- **NHS Protect** 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.
- The **NHS Trust Development Authority** 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 immunization 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

The Wirral CCG and Cheshire CCGs will update this policy to reflect national or regional changes to the definition of Serious Incidents as we are committed to ensuring the best quality healthcare for our local populations and actively working together with colleagues and providers to ensure we meet this principle.

The Wirral and Cheshire CCG's staff members should also consider referencing the following local guidance as part of their management of Serious Incidents:

- [NHS Litigation Authority: Risk Management Standards](#)
- NHS North West: Procedure for Maternity, Infant and Child Incidents Reported on Strategic Executive Information System (StEIS). [Appendix B]
- [National Reporting Learning System \(NRLS\)](#)
- [The CCG Assurance 2013/14 – Operational Guidance](#)

4. Terminology

4.1 Serious Incident

General Definition

The Revised 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 on going 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 harm⁶ 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 multiple linked or unlinked events signalling systemic failures within a commissioning or health system.

Circumstances where a Serious Incident must be declared

⁶NHS 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-incident-framework-upd.pdf>

NHS England has produced a list that sets out the circumstances in which a Serious Incident must be declared. Providers are therefore asked to consider each incident on a case-by-case basis using the description below.

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
 - Unexpected or avoidable death⁷ 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 past⁸
 - 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 occurring⁹; or
 - where abuse occurred during the provision of NHS-funded care.

This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident¹⁰

- A Never Event - all Never Events are defined as Serious Incidents although not all Never Events necessarily result in serious harm or death;¹¹

⁷ NHS England define this as 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.

⁸ NHS England confirm that this 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. Appendix 1 of the framework provides further detail <http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framework-upd.pdf>

⁹ NHS England state 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.

¹⁰ Further guidance is available in Part One; sections 1.3 and 1.5 of the framework <http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framework-upd.pdf>

¹¹ NHS England define Never Events as arising from failure of strong systemic protective barriers which can be defined as successful, reliable and comprehensive safeguards or remedies e.g. a uniquely designed connector to prevent administration of a medicine via the incorrect route - for which the importance, rationale and good practice use should be known to, fully understood by, and robustly sustained throughout the system from suppliers,

- 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 issue¹²;
 - Property damage;
 - Security breach/concern;¹³
 - Incidents in population-wide healthcare activities like screening¹⁴ 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 services¹⁵); or
 - Activation of Major Incident Plan (by provider, commissioner or relevant agency)¹⁶
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation¹⁷

Local Serious Incident Lists

The Wirral CCG and Cheshire CCGs do recognise that the Revised Framework states that there is no definitive list of events or incidents that constitute a Serious Incident and commissioners should not create local lists as they can lead to inconsistent or inappropriate incident management.

While the Wirral CCG and Cheshire CCGs recognise NHS England's concerns, to ensure consistency in reporting across Wirral and Cheshire it has been agreed collaboratively that a list should be included within this policy to act as a prompt for provider organisations. This list is included at appendix A, and has been adapted from the previously agreed NHS England/NPSA reporting criteria and thresholds for serious incidents. The Wirral CCG and Cheshire CCGs do however accept that such a list is not exhaustive and should not be the

procurers, requisitioners, training units, and front line staff alike. See the Never Events Policy and Framework available online at: <http://www.england.nhs.uk/ourwork/patientsafety/never-events/>

¹² See Appendix 2 for further information at <http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framwrk-upd.pdf>

¹³ NHS England confirms that this will include absence without authorised leave for patients who present a significant risk to themselves or the public.

¹⁴ [Interim Guidance for Managing Screening Incidents \(2015\)](#)

¹⁵ NHS England recognise that in some cases ward closure may be the safest/ most responsible action to take but in order to identify problems in service/care delivery, contributing factors and fundamental issues which need to be resolved an investigation must be undertaken

¹⁶ For further information relating to emergency preparedness, resilience and response, visit: <http://www.england.nhs.uk/ourwork/epr/>

¹⁷ NHS England confirms that 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.

only mechanism by which Serious Incidents are defined and would urge providers to work closely with their relevant CCGs if they are ever in doubt of whether an incident meets the threshold of being a Serious Incident.

The Wirral CCG and Cheshire CCGs agree, in principle that the focus should be on investigating incidents with the most significant opportunities for learning and preventing future harm. The Wirral CCG and Cheshire CCGs also fully endorse the Revised Framework's recommendation that in cases where it is unclear whether any weaknesses in a system or procedure caused or contributed to a serious outcome, the most defensible position is to discuss openly, investigate proportionately and to let the investigation decide.

The Wirral CCG and Cheshire CCGs recognise that if a Serious Incident is declared but further investigation reveals that the definition of a Serious Incident is not fulfilled- for example there were no acts or omissions in care which caused or contributed towards the outcome the incident can be updated and closed. The Wirral CCG and Cheshire CCGs would however ask Providers to ensure that they are fully involved in the decision making process.

4.2. Levels of Investigation

The level of response required in response to a Serious Incident varies on a case-by-case basis. Providers should therefore be assessing each incident to determine whether it requires the following levels of investigation:

- **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.

4.3 Principles of Serious Investigation Management

NHS England endorses seven key principles for the management of all Serious Incidents.¹⁸



5. Procedure following a Serious Incident

1. Review

1.1 When a Serious Incident occurs, the provider must declare the incident on the Strategic Executive Information System (StEIS) within two working days of identification. The Provider should also undertake any appropriate immediate actions¹⁹ and assess whether other bodies should be notified as detailed at section 3. If the provider does not have access to StEIS, then written notification must be sent to the Wirral CCG within 48 hours to allow the CCG to add this on to StEIS.

¹⁸ See pp.21-24 for full definitions of these principles <http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framework-upd.pdf>

¹⁹ As set out at pp.32-35 of the National Framework

1.2 If the provider is unclear as to whether the incident meets the definition of a Serious Incident, contact should be made with the nominated person at the CCG 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 and share with the appropriate Serious Incident Group for their information/ratification.

1.3 The CCG will receive notification of a new Serious Incident via the StEIS alert system. The information contained within the alert should be recorded on DATIX and an update added to StEIS, with an acknowledgement sent to the provider.

1.4 The provider should undertake a 72 hour review and upload this to StEIS within 3 working days. The aim of the 72-hour review is to:

- Identify and provide assurance that appropriate immediate action has been taken
- Assess the incident in more detail
- Propose the appropriate level of investigation²⁰

1.5 If the commissioner feels the initial notification suggests the incident is large scale or likely to result in national media attention, they must alert NHS England, consider sharing the matter at the Quality Surveillance Group or, if very serious, request a Risk Summit.

2 Investigation Report

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 strategy. The focus of the investigation should be to:

- Gather and map the information
- Analyse the information
- Generate a solution

The provider should also consider involving and supporting affected patients, staff, victims, perpetrators, patients/victims' families and carers.²¹

2.2 The provider should aim to submit the final report and action plan to the appropriate CCG(s) within 60 working days (Level 1 & 2) or 6 months (Level 3 – Independent Investigations). The provider should also consider whether multiple commissioners will require sight of the RCA, such as in cases where one CCG is the lead commissioner for an acute hospital but the patient is registered with an alternative CCG GP practice.

2.3 The CCG should send a reminder to the provider at day 45 (15 days prior to the deadline) for level 1 & 2 or month 5 for level 3 investigations. If a provider requires an extension, this should be requested in writing with full details provided to allow the CCG to review. 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.

2.4 If the investigation report is received within 60 working days, move to stage 2.5. If the investigation report is not received on day 60, a reminder should be sent requesting the RCA as soon as possible. If the investigation report is still not received and an extension request

²⁰ Further guidance for providers is available at p.40 of the Revised Framework

²¹ Further guidance for providers is available at pp.37-40

has not been agreed then then this will be escalated and managed via the regular Contracts meetings which are held with the organisation.

2.5 Once received, the investigation report should be saved in Datix and StEIS, and both updated to reflect receipt and confirm when it is due to be considered by the CCG group. A copy of the RCA should be saved in the appropriate Serious Incident Group Monthly meeting folder so it can be incorporated in to the agenda.

3. Serious Incident Review Group

3.1. The completed RCA will be presented to the relevant CCG Serious Incident Review Group which is a subcommittee of the CCG Governing Body. The role of the Serious Incident Review Group is to quality assure investigation reports and action plans received from providers, in accordance with section 6.2.2.v. The Serious Incident Review Group is also required to monitor any trends and themes in addition to identifying any actions that may require escalation to the Quality, Performance and Finance Committee.

3.2 While the content of meetings will depend on the papers available, when reviewing and discussing the papers the Serious Incident Review group should reference their specific function which is to hold providers to account for the quality and timeliness of the Serious Incident investigation and accompanying action plan. They do this by:

- Ensuring that the Serious Incident report fulfils the required standard for a robust investigation by following a systems-based approach that identifies the correct root causes and contributory factors (where possible to do so) to produce focused recommendations that inform an action plan and accompanying learning that will prevent recurrence.
- Highlighting any concerns or areas that require further action in respect of the investigation or action plan that need to be fed back to the provider
- Agreeing that the actions set out in the accompanying action plan will eliminate or reduce the risk of recurrence.
- Determining a schedule to monitor and review the providers implementation of the action plan
- Making recommendations to close the incident when the group are satisfied that above requirements are satisfied, referencing the appropriate closure checklist in reaching these judgements
- Identifying themes, trends or Serious Incidents that require escalation to the Clinical, Quality and Performance Committee and/or the relevant Provider Quality and Performance Meetings.

3.4 The Serious Incident Review Group can close an incident before all preventative actions have been implemented and review; particularly where these are continuous or long term and the commissioner has received evidence that the actions have been initiated. Commissioners should however put in place robust arrangements to ensure implementation is regularly reviewed. It is good practice for commissioners to agree a mechanism for monitoring and reviewing actions undertaken by providers.

3.4 The Serious Incident Review Group will endeavour to provide feedback to the provider within 30 days. Although the Wirral and Cheshire CCGs note that the framework suggests this is completed within 20 calendar days, 30 days has been agreed as a suitable timescale in Wirral and Cheshire to reflect the current arrangements of monthly Serious Incident Review Group meeting.

4. Follow Up

4.1 Following the meetings, Datix and StEIS records should be updated to reflect any discussions or action points identified by the Serious Incident Review group for each Serious Incident. Relevant deadline and action activities should also be completed for each Datix record to assist with the monitoring. In the case of action plans, the next activity will be dependent on what the group identified as a suitable period for monitor and review

4.2 Providers should then be provided with a report of their open Serious Incidents, with key actions or feedback highlighted with appropriate deadlines. This should be sent within five working days of the meeting to enable suitable time for the provider to prepare for the following months meetings.

4.3 Providers should share with the relevant CCGs any evidence in response to feedback or to demonstrate completed action plans to the dedicated Serious Incident inbox. Details of responses and actions taken should also be recorded in the relevant STEIS and Datix records

5. Closure

5.1 If the Serious Incident Review group confirm they are happy to close the investigation the lessons learned from the investigation report should be added to the 'description' field in Datix and an appropriate sentence recorded. The closed date field should then be completed..

5.2 The root causes and lessons learned should also be copied into StEIS before the record is closed.

5.3 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.

6. Roles and Responsibilities

6.1 Provider

6.1.1 General Responsibilities

The primary responsibility for Serious Incidents is from the provider of the care to the people who are affected or their families/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.

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 the commissioner of the care where the incident took place.

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

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

- That early, meaningful and sensitive engagement with affected patients and staff
- Clear procedures are in place for taking immediate action following Serious Incidents
- That trained and resourced staff are available 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
- To follow up and monitor action plans until they are completed. Support investigations being led by external agencies
- Supports 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,.

6.2 Wirral CCG

6.2.1. General Responsibilities

Wirral CCG must assure themselves of the quality of services commissioned and hold providers to account for their responses to Serious Incidents, by quality assuring the robustness of their provider's investigation and action plan implementation. In cases where operational management of Serious Incidents has been delegated to Commissioning Support Units, the CCG retains overall accountability.

Wirral CCG will:

- Use Serious Investigation Reports along with other information and intelligence, to inform actions that continuously improve services and share that information with relevant regulatory and partner organisations.
- Support providers should they suffer any gaps in resources, capacity, accessibility or expertise to undertake a Serious Incident investigation.
- Work with providers and facilitate discussions about which organisation should take responsibility for co-ordinating the Serious Incidents in matters which involve multiple providers. This could include individual CCGs leading the investigation if the circumstances suggest this may be warranted.
- Develop and agree procedures for managing concerns raised to them about the management of the investigation process.

Wirral CCG will also have procedures for managing Serious Incidents that occur within their own organisations which will include a mechanism to support Quality Assurance and closure of investigation reports.

6.2.2. Internal Responsibilities

i. Corporate Officer (Compliance)

Reviewing and uploading all STEIS alerts received to Datix within two working days of receipt.

Maintaining and updating the data about each Serious Incident on Datix and StEIS

Monitoring Serious Incident deadlines and liaising with providers to ensure a timely response, escalating any delays to Lead Nurse Quality & Patient for consideration.

Acknowledging receipt of completed investigation reports and sharing any feedback from the Serious Incident Review Group to providers.

Escalating any extension requests to the Lead Nurse Quality & Patient Safety and Director Quality & Patient Safety

Collating and preparing the Agenda Papers for the monthly Serious Incident Review group.

Compiling and circulating the minutes and action log following each Serious Incident Review group.

Supporting the Lead Nurse Quality & Patient Safety in undertaking the required actions identified at each Serious Incident Review group

Generating reports from Datix about the Serious Incidents which will include monthly RAG rated reports to providers and the Serious Incident Review Group in addition to any ad hoc reports that may be requested by the members of the Serious Incident Review Group and/or other CCG individuals.

Liaising with other CCGs in multi-commissioner Serious Incidents.

ii. Lead Nurse Quality & Patient Safety

Overseeing and supporting the Corporate Officer in undertaking the day to day management of the Serious Incident workload.

Reporting to the Serious Incident Review Group the status and actions taken in respect of the Serious Incident workload on a monthly basis, including escalating any timeliness or quality concerns to Director Quality & Patient Safety and/or Medical Director

Undertaking actions requested by the Serious Incident Review group.

Escalating Serious Incident Review Group matters to the Quality Performance and Finance Committee when indicated.

Reviewing and approving any extension requests that may be received from providers, in collaboration with the Director Quality and Patient Safety

In accordance with section 1.1 of the NHS England National Framework²², reviewing any incidents that providers are either unsure is a Serious Incident or feel no longer meet the threshold, taking advice from the appropriate Serious Incident Review Group members (where applicable) and recording all discussions and any decision rationale

²² See pages 14-16: <http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framwrk-upd.pdf>

Supporting providers where timeliness or quality concerns have been identified in Serious Incident work.

Attendance at relevant meetings with providers, neighbouring CCGs and NHS England to review trends and best practice in Serious Incident work.

Review and update relevant guidance to reflect changing policy and practice as and when required.

iv. Serious Incident Review Group

Holding providers to account for the quality and timeliness of their Serious Incident investigations and accompanying action plans by:

- Reviewing and monitoring all Serious Incidents that occur within services commissioned by Wirral CCG
- Ensure that a robust and timely investigation is undertaken by providers that will include the review of systems and processes relating to the incident
- Ensuring that the Serious Incident report fulfils the required standard for a robust investigation by following a systems-based approach that identifies the correct root causes and contributory factors (where possible to do so) to produce focused recommendations that inform an action plan and accompanying learning that will prevent recurrence.
- Agree that the actions set out in the accompanying action plan will eliminate or reduce the risk of recurrence.
- Highlighting any concerns or areas that require further action in respect of the investigation or action plan that need to be fed back to the provider
- Monitoring and regularly reviewing the providers implementation of the action plan
- Making recommendations to close the incident when the group are satisfied that above requirements are satisfied, referencing the appropriate closure checklist in reaching these judgements
- Identifying themes, trends or Serious Incidents that require escalation to the Quality, Performance and Finance Committee and/or the relevant Provider Quality and Performance Meetings.
- Agreeing a mechanism for the monitoring and review of learning amongst providers that is highlighted in action plans.

v. Quality Performance and Finance Committee

Receive notification of:

- Minutes from the previous month's Serious Incident Group meeting
- Incidents being reported via the STEIS system;
- Outstanding issues not implemented during the agreed timescales to ensure provider organisations take appropriate action;
- Concerns regarding the quality of the reports received.

7. Agreed Principles for Wirral CCG

Wirral CCG has agreed to adopt the following principles in managing Serious Incidents that occur within local providers:

- Wirral CCG will focus on 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.
- Wirral CCG may be required to performance manage or regulate organisations on the basis of their responses 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.
- Wirral CCG will not, however, performance manage or regulate organisations on the basis of the number they report and agree with the national framework that this could discourage reporting and inhibit learning. Wirral CCG will 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.

8. Further Guidance and Reading

Appendix A – WCCG Categories for reporting on to StEIS (Adapted from: National Patient Safety Agency (NPSA) Reporting Criteria and Thresholds for Serious Incidents). This list is not exhaustive and will be reviewed annually.

| Incident Type | Threshold |
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| Abscond | <p>Escape from within the secure perimeter of medium or high security mental health services by patients who are transferred prisoners Secure Unit Patient who is a transferred prisoner escaping from medium or high secure mental health services where they have been placed for treatment subject to Ministry of Justice restrictions. (NE: <i>Escape of a transferred Prisoner</i>) Patients detained under the Mental Health Act, and current risk assessment confirms current risk of:</p> <ul style="list-style-type: none"> • violence/risk to others • self-harm • neglect • exploitation (vulnerable adult) <p>Informal patient and current risk assessment confirms current risk of:</p> <ul style="list-style-type: none"> • violence/risk to others • self-harm • neglect • exploitation (vulnerable adult) |
| Accident Whilst in Hospital | <p>Accident on NHS premises or whilst receiving NHS funded care which results in:</p> <ul style="list-style-type: none"> • permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy <p>This includes entrapment of an adult in bedrails (NE: <i>Entrapment in bedrails</i>) Patient scalded by water during bathing (NE: <i>Severe scalding of patients</i>)</p> |
| Admission of under 18s to adult mental health ward | <p>Include all admissions of an under 18 yr. old to an adult MH inpatient unit. Include the actual age of service user and the reason for admission describing if the admission was required because of clinical need or lack of a bed in an age appropriate setting or staffing levels.</p> |
| Admission of under 16s to adult mental health ward | <p>To include under 18 admissions CAMHS clients. Include the actual age of service user and the reason for admission describing if the admission was required because of clinical need or lack of a bed in an age appropriate setting or</p> |

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| | staffing levels. |
| Adverse media coverage or public concern about the organisation or the wider NHS | <p>Incidents where there may not be permanent harm or death but result in a repeated pattern of negative media attention for the organisation for example:</p> <ul style="list-style-type: none"> • An incident is reported in more than one local paper and television or national media and the organisation is being criticised for the quality and safety of patient care. <p>This does not include workforce, financial issues for example where the impact is on an employed individual and does not affect patient care</p> |
| Allegation against HC non-Professional | <p>Where a member of staff shows gross disrespect for the dignity of a patient/deceased patient. Serious:</p> <ul style="list-style-type: none"> • verbal and/or physical aggression • criminal acts involving patients or staff • complaints about a member of staff or primary care contractor or any incident relating to a staff member where significant adverse media interest could occur • breach of confidentiality • fraud <p>Where there are any allegations of abuse against adults who work with children, the incident should also be reported to the Local Authority Designated Officer (as per ***** Children's Board) who has a responsibility to be involved in the management and oversight of individual cases and will also provide advice and guidance to employers and voluntary agencies</p> |
| Allegation Against HC Professional | <p>Where a member of staff shows gross disrespect for the dignity of a patient/deceased patient. Serious:</p> <ul style="list-style-type: none"> • verbal and/or physical aggression • criminal acts involving patients or staff • complaints about a member of staff or primary care contractor or any incident relating to a staff member where significant adverse media interest could occur • breach of confidentiality • fraud |
| Ambulance Accident - Road Traffic Collision | <p>Where:</p> <ul style="list-style-type: none"> • patients/staff or the public have been harmed and ambulance personnel had contributed to the RTA • there had been a significant impact on business continuity in terms of delays to the assessment and transfer of patients |

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| Ambulance Delay | Where: <ul style="list-style-type: none"> • there had been a significant impact on the assessment and treatment of patients with the potential for permanent harm and ambulance services had contributed to the delay • there had been a significant impact on business continuity in terms of delays to the assessment and transfer of other patients and other organisations had contributed to the delay |
| Ambulance (general) | Permanent harm to one or more patients or staff Local media – long term – moderate effect – impact on public perception of Trust and staff morale National media >3 days – public confidence in organisation |
| Assault (unknown assailant) | Physical harm to one or more patients or staff Local media causing long term or moderate effect regarding impact on public perception of Trust and staff morale. National media >3 days affecting public confidence in organisation |
| Attempted Homicide by Inpatient (in receipt of mental health services) | Inpatient in receipt of mental health services who tries to kill another person |
| Attempted Homicide by Inpatient (not in receipt of mental health services) | Inpatient who is not in receipt of mental health services who tries to kill another person, e.g. a patient being cared for in acute or primary care |
| Attempted Homicide by Outpatient (in receipt of mental health services) | Outpatient in receipt of mental health services who tries to kill another person |
| Attempted Homicide by Outpatient (not in receipt of mental health services) | Outpatient who is not in receipt of mental health services who tries to kill another person, e.g. a patient being cared for in acute or primary care |
| Attempted Suicide by Inpatient (in receipt of mental health services) | An inpatient in receipt of mental health services who tries to kill themselves |
| Attempted Suicide by Inpatient (not in receipt of mental health services) | An inpatient who is not in receipt of mental health services who tries to kill themselves, e.g. a patient being cared for in acute or primary care |
| Attempted Suicide by Outpatient (in receipt of mental health services) | An outpatient in receipt of mental health services who tries to kill themselves |
| Attempted Suicide by Outpatient (not in receipt of mental health services) | An outpatient who is not in receipt of mental health services who tries to kill themselves, e.g. a patient being cared for in acute or primary care |
| Bogus Health Workers | Permanent harm to one or more patients Local media – long term – moderate effect – impact on public perception of Trust and staff morale National media >3 days – public confidence in organisation |

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| Child Abuse (family) | Abuse with one or more children within the family context (this would include adopted and looked after children in a foster care setting) Reportable to Wirral Safeguarding Children's Board |
| Child abuse (institutional) | Abuse of one or more children by one or more perpetrators in an institutional setting where there is a health professional linked to the institution (this would include a school, nursery, child minder etc.) and children who are looked after in a residential setting or an inpatient in a health care setting Reportable to Wirral Safeguarding Children's Board |
| Child Abuse (multiple) | Networked abuse with one or more children by one or more perpetrators e.g. paedophile ring, child trafficking etc. Reportable to Wirral Safeguarding Children's Board |
| Child Death | Unexpected child death up to 17 years and 364 days Where there may be suspicious circumstances: See Appendix B Reportable to Wirral Safeguarding Children's Board |
| Child Serious Injury | Where there is permanent harm that doesn't involve safeguarding or abuse and where there is a link to health services, for example on health service premises, whilst undergoing health treatment, etc. |
| Communicable Disease and Infection Issue | Outbreaks of infection that involve presumed transmission within healthcare settings <ul style="list-style-type: none"> • cases/outbreaks of infection with an NHS-attributable food, water or environmental source • case of blood borne or other virus infection in a healthcare worker or patient that necessitates consideration of a look-back exercise • failed vaccination cold chain affecting significant numbers of patients • call and recall system failures affecting significant numbers of patients • exposure to chemical agents or radiation caused by failures in healthcare settings |
| Confidential Information Leak | Major breaches of confidentiality such as the loss or theft of personal identifiable records or information, hard copy or electronic An incident involving the actual loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious this includes incidents rated 3-5. Grade 3: Serious breach of confidentiality e.g. up to 100 people and/or damage to a services reputation/low key media coverage Grade 4: Serious breach with either particular sensitivity e.g. sexual health details, or up to 1,000 people affected and/or damage to an organisations reputation/media coverage |

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| | Grade 5: Serious breach with potential for ID theft over 1,000 people affected and/or Damage to NHS reputation/National media coverage Incidents rated as 1 and 2 should also be reported as grade 0 for notification only. |
| C.Diff and Health Care Acquired Infections | Which results in: <ul style="list-style-type: none"> • death or permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention which will shorten life expectancy |
| Delayed diagnosis | This includes missed and mis-diagnosis, and delays in out-patient appointments which results in: <ul style="list-style-type: none"> • permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention will shorten life expectancy |
| Drug Incident (general) | To include Medication Never Events: <ul style="list-style-type: none"> • Wrongly prepared high-risk injectable medication (new) • Maladministration of potassium-containing solutions (modified) • Wrong route administration of chemotherapy (existing) • Wrong route administration of oral/enteral treatment (new) • Intravenous administration of epidural medication (new) • Maladministration of Insulin (new) • Overdose of midazolam during conscious sedation (new) • Opioid overdose of an opioid-naive patient (new) • Inappropriate administration of daily oral methotrexate Resulting in: <ul style="list-style-type: none"> • permanent harm or death to one or more patients, where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy And <ul style="list-style-type: none"> • Wrong gas administered or failure to administer any gas (NE: Wrong gas administered) • Intravascular air embolism introduced during IV infusion/bolus dose or through haemodialysis circuit.(NE: Air embolism) |
| Failure to act upon test results | Where the failure results in: <ul style="list-style-type: none"> • permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy |

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| Failure to obtain consent | Where the procedure or treatment results in: <ul style="list-style-type: none"> • permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy |
| Health and Safety | Which resulted in closure of a facility which had consequences for business continuity: <ul style="list-style-type: none"> • Chemical incident • Fire • Accident on NHS premises which results in: <ul style="list-style-type: none"> o permanent harm to one or more staff, visitors or members of the public where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy |
| Homicide by Inpatient (in receipt) | For use where HSG Guidance applies |
| Homicide by Inpatient (not in receipt) | For use where HSG Guidance applies |
| Homicide by Outpatient (in receipt) | For use where HSG Guidance applies |
| Homicide by Outpatient (not in receipt) | For use where HSG Guidance applies |
| Hospital Equipment Failure | Hospital estate infrastructure which leads to: <ul style="list-style-type: none"> • Sustained loss of service which has serious impact on delivery of patient care resulting in major contingency plans being invoked • Sustained loss of service which has serious impact on delivery of patient care resulting in major contingency plans being invoked |
| Infected Health Care Worker | Infected healthcare worker where the infection was not known and no controls were in place with a reportable communicable disease e.g. TB, measles etc. |
| Maternity services - intrapartum death | For an intrapartum death (24+ weeks gestation) that is: <ul style="list-style-type: none"> • Unexpected and Suspicious • Where there are clear failings by health (See definitions in Appendix B: Maternity, Infant and Child Incidents Reported on STEIS Procedure) |
| Maternity services - intrauterine death | For an intrauterine death (24+ weeks gestation) that is: <ul style="list-style-type: none"> • Unexpected and Suspicious • Where there are clear failings by health (See definitions in Appendix B: Maternity, Infant and Child Incidents Reported on STEIS Procedure) |

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| <p>Maternity services - maternal death</p> | <p>For a maternal death that is:</p> <ul style="list-style-type: none"> • Unexpected and Suspicious • Unexpected and Unexplained • Where there are clear failings by health <p>This includes maternal death as a result of post-partum haemorrhage after elective caesarean section (NE: Maternal death due to post-partum haemorrhage after elective Caesarean section.)</p> |
| <p>Maternity services - unexpected neonatal death.</p> | <p>For a neonatal death (a child that dies between 0 to 28 days) that is:</p> <ul style="list-style-type: none"> • Unexpected and Suspicious • Unexpected and Unexplained • Where there are clear failings by health <p>(See definitions in Appendix B: Maternity, Infant and Child Incidents Reported on STEIS Procedure)</p> |
| <p>Maternal unplanned admission to ITU</p> | <p>Where a mother is unexpectedly admitted to intensive care either following or prior to birth when admitted for delivery.</p> |
| <p>Suspension of Maternity Services</p> | <p>Any time a decision is made to suspend the full maternity service even if suspension is subsequently not possible.</p> |
| <p>Unexpected admission to NICU</p> | <p>Any formal admission to NICU of a baby:</p> <ul style="list-style-type: none"> • born between 37-41 weeks gestation • for whom there is no documented plan for admission to a neonatal unit prior to birth • and who require admission at birth or in the early neonatal period (up to 48 hrs from time of birth). <p>Exclusions:</p> <ul style="list-style-type: none"> • Implementation of a locally agreed neonatal care pathway, which enables identification of babies at risk of admission to NICU due to specific identified factors prior to birth is acceptable to agree exclusion of such cases. • For maternity units where the service model does not include transitional cots on the post-natal ward, where there is a need for short-term assessment in the NICU, not progressing to a formal admission, these cases would be excluded. <p>Where there is clear documentation in the mother's medical notes prior to birth that factors have been identified that indicate a potential for admission to NICU, these cases are excluded.</p> |

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| Medical equipment failure | <p>This means medical devices (not hospital infrastructure) which leads to:</p> <ul style="list-style-type: none"> • Permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy • Sustained loss of service which has serious impact on delivery of patient care resulting in major contingency plans being invoked |
| Mental Health Act - Class B incident | <p>Mental Health Act incidents except deaths. These are incidents that are not life threatening, but which acutely jeopardise the wellbeing of the patient. They include but are not limited to, allegations of patient abuse or neglect, sexual assaults, racial assaults, attempted suicide, aggravated assaults, unexplained injuries and serious medication errors</p> |
| Other (Please specify within incident description) | <p>Misidentification Error Death or severe harm as a result of administration of the wrong treatment following inpatient misidentification due to a failure to use standard wristband (or identity band) identification processes i.e. those that comply with</p> <p>Mixed Sex Accommodation Reporting of any unjustified mixing of genders (i.e. breaches) in sleeping accommodation by providers of NHS funded health care.</p> <p>Trolley Waits over 12 hours The waiting time for an emergency admission via A & E is measured from the time when the decision is made to admit, or when treatment in A & E is completed (whichever is later) to the time when the patient is admitted.</p> <ul style="list-style-type: none"> • Time of decision to admit is defined as the time when a clinician decides and records a decision to admit the patient or the time when treatment that must be carried out in A & E before admission is complete – whichever is the later. |
| Pressure Ulcer Grade 3 AND Pressure Ulcer Grade 4 | <p>Please follow Pressure Ulcer Flow Chart (Appendix C).</p> <p>Avoidable Pressure Ulcer:</p> <ul style="list-style-type: none"> • All hospital and community acquired Grade 3 and 4 pressure ulcers should be reported on StEIS by the NHS provider. Please indicate whether it is community or acute sector acquired by using the Care Sector drop down on StEIS and include it in the description field. • Primary care acquired pressure ulcers in commissioned independent providers should be reported on StEIS by the commissioning organisation this includes care commissioned in nursing or residential care homes. • Incident found in patients own homes where there is no input from any health services should be reported to the |

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| | <p>commissioner and internal analysis undertaken of any significant trends. These do not need to be reported on StEIS.</p> <ul style="list-style-type: none"> • All Grade 3 and 4 Pressure Ulcer Incidents should be assessed for evidence of neglect or abuse and if this is substantiated the Trust must report this to the Local Safeguarding Board and the Care Quality Commission (CQC) as well as on StEIS, the assessment should be concluded within a maximum of 21 days. |
| Safeguarding vulnerable adult | <p>Where an individual suffers permanent harm or death as a result of a safeguarding vulnerable adults issue where they are in receipt of health care services (except GPs). Grade 3 and 4 Pressure Ulcer Incidents may be an indicator of neglect or abuse, if this is substantiated as part of the investigation then please report using the Safeguarding vulnerable adult incident type on StEIS.</p> |
| Screening Issues | <p>To be used for national screening programmes only. An actual or possible failure at any stage in the screening pathway that exposes the programme to unknown levels of risk that screening, assessment or treatment has been inadequate, and that as a result there are possible serious consequences for the clinical management of patients. The level of risk to an individual may be low but, because of the large numbers involved, the corporate risk may be very high.</p> <p>The screening programmes covered are:</p> <ul style="list-style-type: none"> • breast cancer • cervical screening • bowel cancer • diabetic retinopathy • abdominal aortic aneurysm • foetal anomaly (including Downs) • infectious diseases in pregnancy • sickle cell and thalassaemia • new-born blood spot • new-born hearing • new-born and infant physical examination |
| Security Threat | <p>Sustained loss of service resulting in major contingency plans being invoked Local media causing long term or moderate effect causing impact on public perception of Trust and staff morale National media >3 days affecting public confidence in organisation MP concerned (questions in the House)</p> |
| Serious Incident by Inpatient (in receipt of mental health services) | <p>Which leads to:</p> <ul style="list-style-type: none"> • Permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy |

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| | For acute trust this would mean patients who are on special observations provided by a mental health trust. |
| Serious Incident by Inpatient (not in receipt of mental health services) | Which leads to: <ul style="list-style-type: none"> • Permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy <p>For mental health trusts this would be for those who are absent, on leave, during transfer etc.</p> |
| Serious Incident by Outpatient (in receipt of mental health services) | Which leads to: <ul style="list-style-type: none"> • Permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy. • Severe harm to a mental health inpatient as a result of a suicide attempt using non-collapsible curtain or shower rails. (NE: Suicide using non-collapsible rails) |
| Serious Incident by Outpatient (not in receipt of mental health services) | Which leads to: <ul style="list-style-type: none"> • Permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy |
| Slips/Trips/Falls | A slip, trip or fall which occurred on NHS premises or whilst receiving NHS funded care which results in: <ul style="list-style-type: none"> • Permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy • This includes falls from unrestricted windows (NE: Falls from unrestricted windows) • All falls that result in the pathway of care being altered and resulting in a longer length of stay. |
| Sub-optimal care of the deteriorating patient | Where the deterioration was not recognised or not acted upon and this has led to permanent harm or death. This includes failure to monitor vital signs or respond including failure to respond to oxygen saturation levels in a patient undergoing general or regional anaesthesia or conscious sedation for a healthcare procedure (NE: Failure to monitor and respond to oxygen saturation) |
| Surgical Error | Which leads to: <ul style="list-style-type: none"> • Permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy. (NE: Wrong site surgery)(NE: Wrong |

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| | <p>implant/prosthesis/Misplaced naso- or oro-gastric tubes)</p> <ul style="list-style-type: none"> • Retained foreign object post-operation, excluding objects that are found to be missing prior to completion of surgery where further action to remove would be more damaging (NE: Retained foreign object post-operation) • Death or severe harm arising from inadvertent ABO mismatched solid organ transplantation. Excluded are scenarios in which clinically appropriate ABO incompatible solid organs are transplanted deliberately. In this context, 'incompatible' antibodies must be clinically significant. If the recipient has donor-specific anti-ABO antibodies and is therefore likely to have an immune reaction to a specific ABO incompatible organ, then it would be a "never event" to transplant that organ inadvertently and without appropriate management. (NE: Transplantation of ABO or HLA incompatible organs) |
| Transfusion Incident | <p>Which leads to:</p> <ul style="list-style-type: none"> • Permanent harm to one or more patients where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy <p>This includes transfusion of ABO-incompatible blood components, it excludes where ABO-incompatible blood components are deliberately transfused with appropriate management. (NE: Transfusion of ABO incompatible blood components)</p> |
| Unexpected Death (general) | <p>Patients, individuals or groups of individuals suffering serious or catastrophic harm or unexpected death whilst in receipt of health services.</p> <p>Domestic abuse homicides where there are children resident or where the domestic abuse was known by health care professionals</p> |
| Unexpected Death of Inpatient (in receipt of mental health services) | <p>Unexpected death of an inpatient who is in receipt of mental health services (i.e. a patient being cared for in acute or primary care) Death of a mental health inpatient as a result of a suicide attempt using non-collapsible curtain or shower rails. (NE: <i>Suicide using non-collapsible rails</i>)</p> |
| Unexpected Death of Inpatient (not in receipt of mental health services) | <p>Unexpected death of an inpatient who is not receipt of mental health services (i.e. a patient being cared for in acute or primary care) that does not fit the category of suicide or attempted suicide</p> |
| Unexpected Death of Outpatient (in receipt of mental health services) | <p>Unexpected death of an outpatient who is in receipt of mental health services (i.e. a patient being cared for in acute or primary care) that does not fit the category of Suicide or attempted Suicide</p> |

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| Unexpected Death of Outpatient (not in receipt of mental health services) | Unexpected death of an outpatient who is not receipt of mental health services (i.e. a patient being cared for in acute or primary care) that does not fit the category of Suicide or attempted Suicide. |
| Unexpected death of Community Patient (in receipt of mental health services) | Unexpected death of a community patient who is in receipt of mental health services (i.e. a patient being cared for in acute or primary care) that does not fit the category of Suicide or attempted Suicide |
| Unexpected death of Community Patient (not in receipt of mental health services) | Unexpected death of a community patient who is not receipt of mental health services (i.e. a patient being cared for in acute or primary care) that does not fit the category of Suicide or attempted Suicide |
| Ward / Unit Closure | Which leads to: <ul style="list-style-type: none"> • Sustained loss of service which has serious impact on delivery of patient care resulting in major contingency plans being evoked • Disruption to facility leading to significant 'knock-on' effect across local health economy |

Appendix B: Definitions of the maternity, infant and child incidents reported on StEIS procedure

These definitions have been taken from The Management of Sudden Unexpected Death in Infants and Children (Pan Cheshire LSCB (2009)).

Age:

The legal definition refers to *baby* or *infant* as age up to 2 years and *child* over two and under 18 years of age.

Neonate:

A child aged between 0 to 28 days.

Unexpected death:

Death of a child that was not anticipated as a significant possibility 24 hours before the death or where there was an unexpected collapse leading or precipitating events that led to the death.

Suspicious circumstances:

Factors in the environment, history or examination which may give rise to concern about the circumstances surrounding the death

Examples: non-accidental injury, environment which highlights issues of neglect.

Appendix C: Grade 3 and 4 pressure ulcer flow chart

