TO BE READ BEFORE FOLLOWING THIS POLICY

OP10 Risk Management and Patient Safety Reporting Policy

From 1 November 2023 this policy commences a phase out period, the guidance and principles of the NHS England Serious Incident Framework (2015) were used to write the OP10 Risk Management and Patient Safety Reporting Policy.
The National Patient Safety Strategy is introducing new ways of working in relation to patient safety incidents and investigations under the new Patient Safety Incident Response Framework (PSIRF).

The OP10 Risk Management and Patient Safety Reporting Policy will be replaced once these changes are fully implemented by the Trust.
The change from the Serious Incident Framework 2015 to PSIRF *does not* apply to incidents outside the scope of PSIRF (i.e., incidents not involving a patient), including incidents that relate to:

- Professional standards
- Information governance;
- Health and Safety incidents (that do not highlight a significant patient safety concern);
- Digital and IT;
- Financial investigations;
- Estates and facilities;

These will continue to be managed the way they are now.
The transition from the OP10 Risk Management and Patient Safety Reporting Policy to OP04 Patient Safety Incident Response Policy will commence on 1 November 2023 and is expected to take 3 - 6 months.
Serious incidents occurring before 1 November 2023 will be investigated and closed under the Serious Incident framework (2015), this will then conclude the period of policy overlap.

In summary
Serious Incidents reported prior to 1 November 2023 will continue to be managed under the serious incident framework (2015).

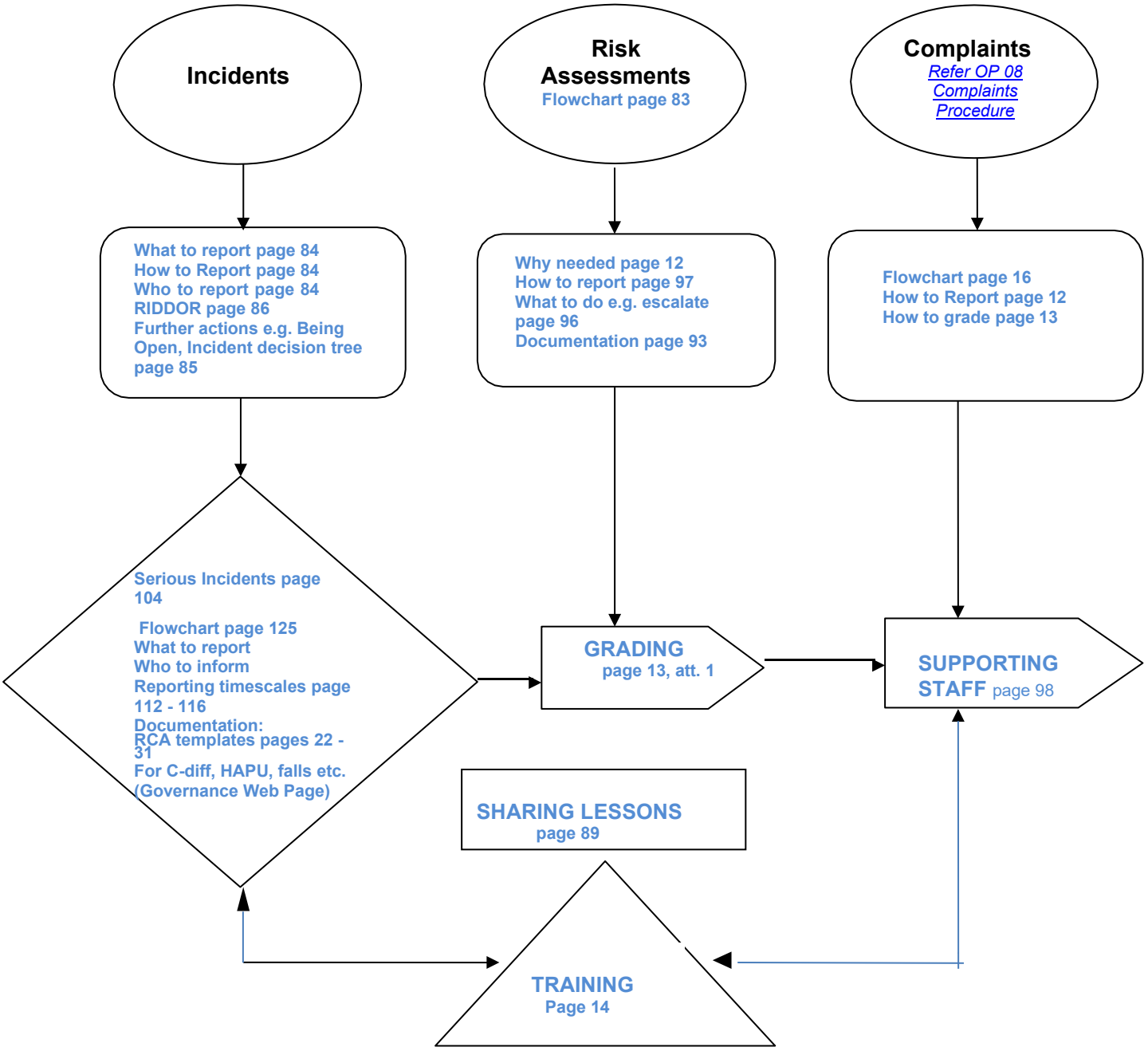
Patient safety incidents reported on or after 1 November 2023 will be managed using the PSIRF Policy.
Reference to both policies for processing should be made accordingly.

OP 10 v17.6

Risk Management and Patient Safety Reporting Policy

Contents **Pages**

Policy Navigation Flowchart



1.0 Policy Statement

1.1 The NHS guidance document 'Building a Safer NHS for patients' and the NHS Long Term Plan identify the need for NHS Trusts to develop a learning culture in which staff are actively encouraged to report incidents and near misses to enable learning and improvement that can be shared across the organisation. Trusts are also expected to adopt sound risk management processes which facilitate learning from complaints, claims, inquests, Prevention of Future death orders, etc. This policy describes the Risk Management processes which enable this.

1.2 This policy applies to all staff employed by The Royal Wolverhampton NHS Trust (RWT) and encompasses the risk management of any incident, risk, claim or complaint affecting patients, clients, staff, volunteers, contractors or visitors (including carers, relatives and advocates).

1.3 This policy aims to provide:

- A framework for all staff to identify, assess, monitor and manage all types of risk;
- Assurance to staff and external bodies that the Trust operates a fair, honest and open (i.e. 'just') culture and that therefore incidents and risks can be freely reported;
- Board assurance regarding the robustness of the Trust risk management processes.

All aspects of this document regarding potential Conflicts of Interest should refer first to the Conflicts of Interest Policy (OP109). In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflict of Interest Policy is to be considered the primary and overriding Policy.

2.0 Definitions Used

For the purposes of this policy the following definitions apply:

2.1 Incident

In terms of risk management any occurrence which has given or may give rise to actual or potential personal injury, property loss or damage, service interruption or adverse publicity, for the Trust, its employees, patients or visitors.

2.2 Near Miss

A near miss is any incident which was prevented from reaching its conclusion, either by active intervention or by 'good luck/fortune'. These incidents must be reported even if there has been no adverse outcome since they provide the Trust with learning opportunities.

2.3 Patient Safety Incident

This is any unintended or unexpected incident that could have or did cause harm for one or more patients receiving NHS-funded healthcare.

2.4 Serious Incidents

Serious incidents (SI) in healthcare are incidents that have the consequences to patients, families and carers, staff or organisations that are either so significant or have such great learning, that a heightened level of response is justified. Within national guidance Serious Incidents are also referred to as Serious Incidents. Requiring Investigation (SIRI) or Serious Untoward Incident (SUI); all have the same meaning and require the same necessary action. Within this policy serious incidents will generally be referred to as SIs. Commissioners must be informed of as SI within 2 working days of the incident being discovered (via the Strategic Executive Information System (STEIS) system).

Serious incidents include acts or omissions in care occurring within NHS-funded services that result in:

- **Unexpected (i.e. where natural causes are not suspected (NPSA 2010) or avoidable death** of one or more patients, staff, visitors or members of the public;
- **Unexpected or avoidable injury resulting in serious harm** (including those where the injury required treatment to prevent death or serious harm);
- **Allegations of Abuse** (against patients occurring on Trust premises/perpetrated by staff);
- A **Never Event;**
- Incidents that **prevent or threaten to prevent a provider organisation's ability to continue to deliver healthcare services;**
- Incidents that cause **widespread public concern** resulting in loss of confidence in healthcare services e.g. media coverage.

***NB for further detail on SI categorisation see** Protocol 2 Reporting and Investigation of Serious Incidents.

2.5 Never Events

Never Events are defined as Serious Incidents that are wholly preventable because 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. Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes.

Each Never Event type has the potential to cause serious patient harm or death. However, it is not necessary for **serious harm or death** to result from an incident for it to be categorised as a Never Event. It is important that when a Never Event occurs, regardless of the outcome, the problems in care are identified and analysed through full investigation using a systems-based investigation method (such as root cause analysis – RCA) to understand how and why they occurred (from a systems perspective) and to ensure effective and targeted action can be taken to prevent recurrence.

The **detailed list of never events** is applicable for incidents that occur on or after 1st April 2015 and is seen **in** Protocol 2 appendix 1. Further update was made in May 2019 to clarify that 'local anaesthetic blocks for dental procedures' is excluded from the 'wrong site surgery' category of Never Event and in February 2021the Removal of wrong teeth was added to the list of excluded incidents (i.e. removed from the Never Events list).

2.6 Major Surgery

A surgical operation within or upon the contents of the abdominal or pelvic, cranial or thoracic cavities or a procedure which, given the locality, condition of patient, level of difficulty, or length of time to perform, constitutes a hazard to life or function of an organ or tissue (if an extensive Orthopaedic procedure is involved, the surgery is considered 'major') - (National Reporting and Learning Framework - NPSA April 2010).

2.7 Being Open

Open communication of patient safety incidents that result in harm or the death of a patient while receiving healthcare. The Being Open Policy (OP60) promotes a culture of openness in all incidents, however the Trust has a statutory duty to be open with patients involved in safety incidents that result in moderate, severe (major) harm, death or prolonged psychological harm of a patient while receiving healthcare. This open communication/disclosure is in line with the Duty of Candour set out in the Francis Public Enquiry report February 2013.

2.8 NHS – funded Healthcare

Healthcare that is partially or fully funded by the NHS, regardless of where it is delivered.

2.9 Patient Safety

A process by which an organisation makes patient care safer. This must involve risk assessment, the identification and management of patient related risks, reporting and analysis of incidents, and the capacity to learn from and follow up on incidents and implement solutions to minimise the risk of them recurring.

2.10 Levels of harm

- **No harm:** impact prevented – any patient safety incident that had the potential to cause harm but was prevented; or incident occurred but no harm was caused to patients receiving NHS-funded care.
- **Low harm:** any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care.
- **Moderate harm:** any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.
- **Moderate increase in treatment:** an unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care).
- **Severe (major/serious) harm:** any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.
- **Permanent harm:** permanent lessening of bodily functions (sensory, motor, physiological or intellectual) including removal of the wrong limb or organ, or brain damage.

- **Prolonged psychological harm:** psychological harm which the service user has experienced or is likely to experience, for a continuous period of at least 28 days.
- **Death:** any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care.

2.11 Unexpected death

Within this context death is defined as where natural causes are not suspected (ie death was not predicted to be likely in the context of the patient's primary diagnosis, comorbidities and treatment plan). The Trust must investigate to determine if the incident contributed to the unexpected death.

In the context of Learning from Deaths - avoidable mortality or death due to problem/s in healthcare is defined as a death that would not have occurred if different clinical or organisational management had been in place and, or if care had been delivered differently. In other words, it is 'death more likely than not to have been due to problems in the care provided to the patient'. Refer OP87 (Learning from Deaths) Policy.

2.12 Root Cause Analysis (RCA)

A systematic process whereby the factors that contributed to an incident are identified. As an investigation technique for patient safety incidents, it looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which an incident happened. Protocol 2 section 5 and table 2 below defines the levels of RCA investigations for serious and reportable incidents.

2.13 Safeguarding

Ensuring that people live free from harm, abuse and neglect and, in doing so, protecting their health, wellbeing and human rights.

- **Children:** Wolverhampton Safeguarding Children Board (known as Wolverhampton Safeguarding Together) procedures apply to anyone from 0-18 (or 21 if in Local Authority Care). Safeguarding is a term which is broader than 'child protection' and relates to the action the commission take to promote the welfare of children and protect them from harm. Safeguarding is everyone's responsibility. Safeguarding is defined in Working Together to Safeguard Children 2015 as:
  - protecting children from maltreatment
  - preventing impairment of children's health and development
  - ensuring that children grow up in circumstances consistent with the provision of safe and effective care and
  - taking action to enable all children to have the best outcomes
- **Adults**: Wolverhampton Safeguarding Adult Board (known as Wolverhampton Safeguarding Together) procedures apply to anyone over the age of 18 years. Safeguarding Adults can include any work or activity which aims to support adults at risk to retain independence, well-being and choice and to be able to live a life that is free from abuse and neglect.
- Refer to the Safeguarding Children Policy (CP41) and Safeguarding Adults Policy (CP 53).

2.14 Abuse

A violation of an individual's human and civil rights by any other person or persons. Abuse may consist of single or repeated acts. It may be physical, verbal or psychological (e.g. sexual abuse, physical or psychological ill treatment, theft, misuse or appropriation of money or property).

It may be an act of neglect or omission to act (which cause harm or place at risk of harm) or it may occur when a vulnerable person is persuaded to enter into a financial or sexual transaction to which he or she has not consented or cannot consent. Abuse may occur in any relationship and may result in significant harm, or exploitation, of the person subjected to it.

2.15 Mental Capacity Act

The Mental Capacity Act 2005 applies to those 16 years and above and provides a statutory framework for people who lack capacity to make particular decisions for themselves or have capacity and want to make preparations for a time when they may lack capacity in the future. It identifies processes to be followed to ensure treatment with lawful authority for those who lack capacity to give consent for themselves. Lack of capacity must be identified by a formal 2 stage test as follows;

1) Does the person have a disturbance of the mind or brain?
2) Can they understand, retain, weigh up consequences and communicate their decision?

2.16 Deprivation of Liberty Safeguards (DoLS)

The Mental Capacity Act allows restraint and restrictions to be used in a patient who lacks capacity – but only if they are in a person's best interests; if it is a proportionate response to the likelihood and seriousness of the harm and there is no less restrictive alternative. Extra safeguards are needed if the restraint and restrictions used will deprive a person of their liberty and they do not have the capacity to consent. The *Deprivation of Liberty Safeguards* (2007) is an amendment to the Mental Capacity Act 2005. The Trust is a Managing Authority and is required to seek Authorization for the DoL from the Supervisory Body (the Local Authority)

2.17 Risk

The chance of something happening that will have an undesirable impact on individuals and/or organisations. It is measured in terms of likelihood and consequences.

2.18 Risk Management

Identifying, assessing, analysing, understanding and acting on risk issues in order to reach an optimal balance of risk, benefit and cost.

2.19 Information Governance Incident

There is no simple definition of a SI. What may at first appear to be of minor importance may, on further investigation, be found to be serious and vice versa.

As a guide the scope of an Information Governance SI requiring investigation must include one or more of the following:-

- An incident which will typically breach one of the principles of the Data Protection Act and/or the Common Law Duty of Confidentiality;
- This includes unlawful disclosure or misuse of confidential data, recording or

sharing of inaccurate data, information security breaches and inappropriate invasion of people's privacy;

- Personal data breaches which will lead to identity fraud or have other significant impact on individuals;
- Applies irrespective of the media involved and includes both electronic media and paper records relating to staff and service users;
- A Cyber-related incident is anything that will (or has) compromised information assets within Cyberspace. "Cyberspace is an interactive domain made up of digital networks that is used to store, modify and communicate information. It includes the internet, but also the other information systems that support our businesses, infrastructure and services".

2.20 NHS Resolution

National Health Service Resolution (NHSR), the body responsible for managing claims against NHS Trusts.

2.21 Categorisation Matrix (Attachment 1)

The tool used by the Trust to assess the severity of incidents, risks and complaints and thereby prioritise any action required.

2.22 The National Patient Safety Agency (NPSA)

The NPSA is a special Health Authority set up to monitor patient safety incidents, provide support and produce solutions to common patient safety issues. On Friday 1 June 2012 the key functions and expertise for patient safety developed by the NPSA transferred to NHS Improvement (now merged with NHS England).

2.23 Just Culture (Sign up to Safety)

- If you make an error, you are cared for and supported
- If you behave in a risky manner by not adhering to policies, you are asked "why ?" first before being judged
- If you recklessly and intentionally put your patients or yourselves at risk, you are accountable for your actions

2.24 Non STEIS (Strategic Executive Information System) incident

An adverse incident/event reported on Datix that does not meet the criteria for reporting as a serious incident but the Trust has determined will require a RCA investigation to understand root causes and develop learning. A non STEIS incident may be a near miss. A non STEIS incident will be subject to a full RCA, Trust monitoring and sign off process.

2.25 Incidents of interest

An adverse incident/event reported on Datix that does not require a formal RCA but for which the progress and outcome of the local investigation is monitored by ESERG (Executive Significant Event Review Group) and progress is updated to ensure adequate local redress. An incident of interest may be a near miss.

2.26 Local Investigation

An investigation undertaken by the Directorate that is not formally monitored by the Divisional or Executive processes. The investigator will be identified by the Directorate (not necessarily an independent investigator) in which the incident occurred. These investigations will be managed by the local Directorate teams and approved via their local governance processes.

2.27 Healthcare Safety Investigation Branch

The Healthcare Safety Investigation Branch (HSIB) became operational on 1st April 2017. Its purpose is to improve safety through effective and independent investigations that do not apportion blame or liability. It will be selective about the incidents it investigates and will focus on incident types that signal systemic or apparently intractable risks within the local healthcare system as well as cases that may lead to high cost litigation claims, eg. certain never events and incident types such as medication errors.

3.0 Accountabilities / Responsibilities

These are set out in detail in the Governance and Risk Management Framework. They are summarised below.

3.1 Chief Executive Officer

The Chief Executive Officer is accountable to the Trust Board for ensuring that the Executive Management Team meets all of its NHS obligations and legal requirements, including those relating to Patient Safety, Financial Governance, and Health and Safety legislation.

3.2 Chief Nurse

The Chief Nurse has designated executive responsibility for Governance and risk management (including Health and Safety, serious incident Management and Safeguarding) and is required to report via Trust committees to the Management Team and Trust Board.

3.3 Finance Director

The Finance Director has designated responsibility for Financial Risk and reports on areas of financial risk to the Management Team and Trust Board. The Finance Director also fulfils the role of Senior Information Risk Owner (SIRO) ensuring that identified information security risks are followed up and incidents managed.

Fraud

The Trust's Chief Financial Officer has a responsibility to ensure that the Trust has adequate Counter Fraud measures in place to manage the risk of fraud in accordance with the NHS Counter Fraud Authority's Counter Fraud Strategy. The Government Functional Standard 013: Counter Fraud applies to all NHS organisations from 1 April 2021. This standard requires the Trust to carry out a comprehensive local risk assessment on an annual basis to identify fraud, bribery and corruption risks, and have a counter fraud provision that is proportionate to the level of risk identified. Risk analysis is undertaken in line with Government Counter Fraud Profession fraud risk assessment methodology. It is recorded and managed in line with this risk management policy and included on the appropriate risk registers. Measures to mitigate identified risks, such as specific proactive reviews, are included in the annual counter fraud workplan and progress is regularly reported to the audit committee. The local counter fraud specialist (LCFS) will inform the Trust of potential fraud risks so they can be effectively assessed. Where risks are identified these will be included on the Trust risk register so they can be proactively addressed. Similarly, all fraud risks identified by the Trust will be communicated to the LCFS. The audit committee and the Chief Financial Officer are kept abreast of any issues relating to fraud throughout the year. In addition, the Trust will participate in national and local pro-active exercises throughout the year, designed to identify

fraud and reduce the likelihood of specific fraud risks to which it may be vulnerable.

Bribery

The Bribery Act 2010 introduced a corporate offence of failure to prevent bribery by persons working on behalf of a business. However, for the Trust to have a statutory defence to the corporate offence, it must demonstrate that the 6 adequate procedures have been considered, assessed, and where appropriate, measures taken. The 6 adequate procedures are as follows: 1. Proportionate procedures to prevent bribery. 2. Top level commitment. 3. Risk assessment. 4. Due diligence. 5. Communication (including training). 6. Monitoring and review.

3.4 Executive Directors

All Directors have responsibility to ensure all aspects of clinical, corporate and financial risk within their portfolios are assessed and managed and are reported to the Trust Board through the Trust Assurance Framework.

3.5 Non-Executive Board Members (NEDs)

The Non-Executive Board Members are accountable for ensuring Board Assurance is delivered by reviewing the Trusts risk management activity through specific Non Executive review committees, i.e. Audit Committee, Risk Assurance Committee, Finance and Performance forums. NED responsibilities will be reflected in the membership of appropriate committees.

3.6 Head of Governance

The Head of Governance is responsible for the development of the Trust risk management reporting systems which support the Trust Board, managers and staff in their risk management activity relating to Clinical and Corporate risks. The Head of Governance, Divisional Healthcare Governance Managers and identified senior management leads (for specialist organisations e.g. MHRA, HPA, SHOT, HSE etc.) will have delegated responsibility for reporting serious or externally reportable incidents to the appropriate bodies e.g. CQC, NPSA, NHS Improvement/NHS England, CCG, ICO and external specialist bodies.

3.7 Divisional Management - Deputy Chief Operating Officer/ Divisional Heads of Nursing and Midwifery/Divisional Medical Directors

The Divisional Management Team - Deputy Chief Operating Officer (DCOO), Divisional Head of Nursing (DHoN), Head of Midwifery (HoM) and Divisional Medical Director(s) have a designated responsibility for governance and risk management within the areas of their managerial responsibility. The DCOO and the Divisional Heads of Nursing and Midwifery are responsible for the implementation and monitoring of governance and risk management processes within the Division. The Divisional Medical Director has overall accountability and responsibility for governance within the Division, providing strategic direction, clinical leadership and expert guidance to Directorates.

3.8 Healthcare Governance Managers

The Healthcare Governance Managers will work closely with both the Central Governance Team and the Divisional Management Team. The Healthcare Governance Managers are responsible for the development, implementation and maintenance of local governance strategies and the performance of governance systems and outputs within the Division. The Healthcare Governance Managers will ensure that the Division delivers the agreed governance agenda, as outlined within the Risk Management Assurance Framework, and all relating policies, to

demonstrate compliance with national standards and legal requirements. The Healthcare Governance Managers also oversee and monitor the incidents reported within Division ensuring that serious incidents are reported to STEIS and investigated within the Trust standard.

3.9 Directorate and Departmental Managers (**and others with management responsibility)**

Directorate and Departmental Managers are accountable for the local operation of governance, risk management and assurance systems and processes. Including ensuring that risk assessments are conducted, risks identified, recorded and monitored by local governance meetings, and that any risks which cannot be managed at this local level are appropriately escalated to more senior management and/or the next tier of risk register as defined in this policy and the Governance and Risk Management Framework.

Directorate and Departmental Managers are responsible for immediate actions taken in response to incidents, risks, claims and complaints. They must also review and if necessary re-grade incident reports generated within their managerial areas, if necessary with the involvement of the Governance Team. They will be required to investigate incidents, assess, manage and escalate risks, and to follow up actions from serious incidents, audits, inspections or other recommendations including staff compliance/training within their own areas.

3.10 Governance Officer

The Governance Officer co-ordinates and facilitates the delivery of governance processes and outputs at local level. Each Directorate has the support of a Governance Officer who works closely with the Directorate Management Team and has key responsibilities around: incident management, risks, clinical audit, NICE, national guidance, external reviews, patient information, CQC, information governance, safety alerts and general governance management.

3.11 Caldicott Guardian

Is a senior person responsible for protecting the confidentiality of patient and service user information. The Caldicott Guardian is informed of any level 1 or higher incidents in order to support the culture of learning and officer advice. Any ICO reportable incidents will be agreed with both the Caldicott guardian and SIRO.

3.12 Senior Information Risk Owner (SIRO)

The SIRO is responsible for the Trust's overall information risk policy and risk assessment process ensuring we have a robust incident reporting process for information risks. The SIRO reports to the Trust Board and provides advice on the content of the Trust Annual Governance Statement in respect to information risk.

3.13 Individual Employees are responsible for:

- Ensuring safe patient care and experience;
- Maintaining safe systems of work, taking care of their own safety and welfare, and that of patients colleagues and all other persons who may be affected by their acts or omissions; this includes arranging any medical treatment;
- Reporting any incident or near miss to the "person in charge" as soon as possible (the "person in charge" is the person with responsibility for the area concerned at the time the incident or near miss occurs);
- Completing incident forms (either electronically or in hard copy) and taking any immediate remedial action required;

- Completing statement forms as required. (N.B in the event of Legal/Human Resource proceedings or on request of patients or the Coroner, incident investigations and statements may be released with personal details redacted); see the statement writing guidance within Protocol 2;
- Complying with investigation of adverse events (includes leading, attending meetings/interviews, provision of information and taking improvement actions);
- Complying with Trust policy (including attending all relevant training).

3.14 Clinical Commissioning Group (CCG)

The CCG is an external body responsible for performance managing the investigation of SI, agreeing appropriate grading, investigation timescales and decisions to close incidents. CCG form part of the Trust RCA reporting process and SI closure process.

3.15 Executive Significant Event Review Group (ESERG)

The ESERG is an Executive group that ensures that all externally reportable SIs and incidents of clinical concern (including non STEIS and incidents of interest) are comprehensively investigated (as appropriate), with actions to improve and lessons shared.

4.0 Policy Detail

This section describes the framework for risk management (with process detail within the appended procedures).

4.1 **Incident Reporting** forms the cornerstone of the Trust risk management processes. By free disclosure and analysis of untoward incidents the Trust is able to identify areas of significant risk and take appropriate action to reduce them.

All incidents and near misses will be investigated and monitored with the intention of identifying trends and lessons to help prevent recurrence where reasonably practicable. SIs will be reported, graded and investigated in line with NPSA guidance.

For more information see Procedure 1: Reporting and Management of Incidents and Protocol 2: Reporting and investigation of Serious Incidents.

4.2 **Risk Assessments and the Risk Register**. Risk assessment is seen as proactive management of risk. In contrast to incident reporting, it affords the organisation an opportunity to put control measures in place before anything untoward has occurred.

Risk assessment principles must be used at all levels within the organisation with regard to business planning, objective setting and service development, so that all proposed changes are risk-assessed for their potential impact on the quality of care and service provision. Risks are identified from various sources including incidents, complaints, claims, audit, compliance measurement, Key Performance Indicators (KPIs) and other national quality measures.

All staff are required to comply with the risk management process ensuring risks are identified, reported, managed and appropriately escalated to more senior management and/or the next tier of risk register as defined in this policy and the Governance and Risk Management Framework.

For more information see Procedure 2: Risk Assessments and Registers.

4.3 Managing Complaints

Careful examination, investigation and response to complaints provide the Trust with valuable learning when it has not been able to meet the expectations of its service users. It may reveal risks which other governance processes do not show up. Detailed instructions for the investigation and handling of complaints can be found in the Complaints Management Procedure (OP08).

Where a complaint has highlighted areas of harm/ potential harm to patients which meets the SI or Duty of Candour criteria, the relevant processes will be initiated to report and investigate the incident and communicate with patients, relatives and carers. Reference must be made between the circumstances of the complaint findings and the Trust categorisation matrix (levels of harm) to direct further action. Liaison must occur between the Complaints team (or the Directorate) and the Governance Department where there are grey areas.

All service areas must consider information provided by the complaints process alongside other sources of governance information, such as incidents, claims and risks. Lessons learned from complaints where appropriate will be shared at an individual level, discussed at local governance meetings and at Trust governance forums so that improvement can occur at Trust and local levels (Refer: procedure 1 section 2.9).

4.4 **Intelligence from Claims and Coroner Inquests** will inform risk identification and redress actions (including response to NHS Resolution risk/claim profiles and Coroner Prevention of Future Death Orders). The Trust has established a Learning from Experience Group as a forum for the review of incident, complaint, claim, inquest and related intelligence to inform risk management actions. (For the Claims Management Process - refer to Legal Services Policy OP 31).

4.5 **Grading incidents, risks complaints and claims for severity.**

The Trust uses a consistent methodology for risk categorisation based on an adaptation of the Australia / New Zealand Risk Management Standard AS / NZ 4360:1999. All incidents, risk assessments and claims will be graded for severity using the Categorisation Matrix (Attachment 1).

The Matrix measure severity by calculating the consequence and likelihood of an event:

- for incidents, the actual consequence of the incident and how often it is likely to occur;
- for risk assessments, the most likely consequence of the risk being realised and how often it is likely to occur;
- for claims, the apparent or predicted consequence of the claim and likelihood of its impact.

This gives a two-part grading such as 5x4, 4x3 etc., which can then be plotted on the ‘traffic light’ section of the Matrix to give an overall severity grading of green, yellow, amber or red.

The overall severity grading attributed to the incident determines the level of investigation / action required. This is detailed in step 5 of the Categorisation Matrix.

For low to minor risk incidents (typically green but also some yellow incidents) action will be local (except where trend analysis indicate wider issues).

SIs typically fall within the amber or red category however some reportable incidents may be graded yellow and require investigation. All incidents where the

harm is moderate or above will be considered for management as a reportable SI. Refer Protocol 2: Reporting and Investigation of Serious Incidents where the level and timescale for investigation is described in detail.

4.6 **Analysis of Risk Management Information**. The Trust uses Datix as a repository for all information related to incidents, risks, complaints and claims and applies a systematic approach to analysis and aggregation of trends.

Trend analysis of incidents, claims and complaints may reveal risks which have not been identified by scrutiny of individual events. Systematic analysis of trends at local and Trust level is a key part of risk identification and the risk management cycle. Timescales for trends reporting typically pertain to at least a 3 month period with comparison to the previous period/quarter and where appropriate may give reference to previous reporting years.

Divisional and Directorate Teams will receive incident trend reports at least quarterly and will ensure that they are reviewed at appropriate meetings and identified risks are recorded and managed.

A Trust level aggregation of incident, claim and complaint trends is reviewed at the Learning from Experience group (LEG) to identify areas of risk, learning and quality improvement actions. Key outcomes are reported to the Quality and Safety Advisory Group (QSAG). Trust Board receives a 6 monthly Claims and Litigation report to include notable claim trends and any appropriate actions. Trend actions are followed up at local governance meetings and at Trust level via on-going review of the trend effect.

4.7 **Staff support in the event of stressful or traumatic incidents, claims or complaints.** Members of staff who are involved in investigations of adverse incidents and complaints or in allegations of negligence can find it both stressful and traumatic. The Trust recognises this and will support and advise all staff as outlined in Procedure 3: Supporting Staff.

5.0 Financial Risk Assessment

5.1 This policy is implemented within existing resources.

6.0 Equality Impact Assessment

6.1 The initial screening of this policy has not identified adverse / negative impact on any personal protected characteristics (PPC); however it is noted that PPCs are not well recorded on Datix. This must be encouraged to better support the monitoring of the equality impact of this policy. If this document is required in larger print please contact the Governance Department.

7.0 Maintenance

7.1 This policy will be reviewed yearly to ensure alignment with national guidance and local learning and improvement.

8.0 Communication and Training

8.1 This policy will be disseminated after each review via the Trust Management Committee and Senior Manager briefing meetings. Wider dissemination for all staff

will be achieved through management cascade, team briefing, Risk Management e-training, all user bulletins and governance forums. All managers have a responsibility to ensure that staff are informed of new and reviewed policies.

8.2 Refer to the Mandatory Training Policy (OP 41) and the Training Needs Analysis for related training subjects, refresher frequency and relevant staff groups to ensure compliance. The Trust provides the following Risk Management and related training.

8.2.1 Risk Management Training

All new staff receive a handbook outlining Governance/Risk Management processes, contacts, advice and support as part of Trust Induction. Further e-training is available via the Kite site: Risk Management training for all staff and Risk Management training for Senior Managers The training outlines basic governance processes and the employees' role in incident reporting, risk management and related processes. Board members also receive bespoke training via a board development programme

8.2.2 Root Cause Analysis (RCA) Investigation Training

The Trust runs an in-house RCA training programme that can be booked by contacting the Governance Dept on Ext 5114. (see Protocol 2 for guidance on levels of investigation). A register of staff trained to undertake RCA investigations will be maintained within the Governance Department. Initial and refresher training is available via face to face sessions or via Microsoft Teams. RCA refresher training will be required every 3 years.

8.2.3 Datix Risk Management Software

Any member of staff requiring access to Datix must contact the Governance Department. Training is delivered by the Governance IM&T staff.

8.2.4 Risk Assessment Training

Training in the principles and practice of risk assessment is available in-house via face to face session or safety media e learning package. Please contact the Governance Department to access either of these courses.

9.0 Audit Process

Criterion	Lead	Monitoring	Frequency	Committee/ Group
How risk is managed locally	Head of Governance	Trust/Internal Audits on risk management processes within the Divisions (including Governance KPI)	6 monthly	Quality and Safety Advisory (Group)
How all risk are assessed	Head of Governance / Healthcare Governance Managers	Sample review of risk from all levels of risk registers (inc. appropriate escalation, types, grades and review of registers).	6 monthly	Quality and Safety Advisory (Group)

Different levels of investigation appropriate to the severity of the event(s)	Healthcare Governance Managers	SI Performance and compliance	Monthly	Quality and Safety Advisory Group (QSAG)
How action plans are followed up	Healthcare Governance Managers,	Datix SI Action Plan monitoring system SI action Audit	Monthly 6 monthly	Quality and Safety Advisory Group (QSAG) Divisions/ Directorate

10.0 References

10.1 This policy is aligned to latest national guidance on incident reporting, external notifications and investigation.

New guidance

- Midlands Region – The Principles for Infection Prevention & Control in the context of COVID-19 to reduce the risk to patients when requiring planned or emergency care in all healthcare settings and Managing Nosocomial COVID-19 Outbreaks (2/6/20 reviewed July 2020).
- NHSE/I Letter - Healthcare associated COVID-19 infections – further action (24/6/20)
- AIDE-MEMOIRE - Nasogastric tube (NGT) placement checks before first use in critical care settings during the COVID-19 response (13th May 2020)
- Revised guidance for medical practitioners on the Notification of Deaths Regulation (Ministry of Justice March 2020)
- Letter from Senior Coroner Black Country Coroners Court – Dated 20/12/2019 – Re change in requirement to notify the Coroner of all deaths within 24 hours of hospital admission.
- RIDDOR (The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013) – HSE guidance – RIDDOR Reporting of Covid Update April/May 2020 **https://www.hse.gov.uk/coronavirus/riddor/riddor-reporting-further-guidance.htm**
- **Cancer Screening guidance:**

  Managing safety incidents in NHS Screening Programmes (publishing.service.gov.uk)
- NHS Long Term Plan (January 2019) NHS England
- Mental Capacity Act (16th May 2019)

Pre–Existing Guidance

- Never Events Policy and Framework and Never Event Listing January 2018 (updated May 2019)
- **Memorandum of Understanding (MOU)**
- The Future of NHS Patient Safety Investigation (March 2018) – Consultation document

- National Guidance on Learning from Deaths – National Quality Board March 2017
- Learning Candour and Accountability – A review of the way NHS trusts review and investigate the deaths of patients in England - CQC December 2016
- NHS England Serious Incident Framework March 2015
- CQC Guidance for Providers on meeting the Regulations March 2015 - Health and Social Care Act 2008 (Regulated Activities) 2014
- NHS England Never Events Framework 2015 /16
- Care Quality Commission (CQC) Essential Standards for Quality and Safety March 2010
- NHS Security Management Service - Serious Incident Reporting System (SIRS) March 2010
- WMSHA SI Policy July 2010
- WMSHA Missing Persons Guidance September 2011.
- NHSLA Standards 2012/13
- Caldicott 2 recommendations 2014 - around personal data breaches (Chapter 4)
- NPSA Investigative interview guidance 2008
- Building a Safer NHS for patients (Feb 2007) DoH

Reference Number and Policy name: OP10 Risk Management and Patient Safety Reporting Policy	**Version:** 17.6 October 2023	**Status:** Final	**Author responsible:** Deputy Director of Assurance **Director Sponsor:** Group Director of Assurance

Version / Amendment History	Version	Date	Author	Reason
	1	October 2002	Trust Governance Manager	Original Policy
	2	May 2005	Head of Governance and Legal Services	NHSLA requirements
	3	November 2005	Head of Governance and Legal Services	NHSLA requirements
	4	May 2006	Head of Governance and Legal Services	Review and amendments
	5	August 2006	Head of Governance and Legal Services	Review of Policy and process
	6	October 2007	Head of Governance and Legal Services	Review and amendments
	7	October 2009	Head of Governance and Legal Services	To include Never Events

	8	November 2010	Head of Governance and Legal Services	Annual review (including never events)
	9	November 2011	Head of Governance and Legal Services	NHSLA requirement Investigation process
	10	March 2012	Head of Governance and Legal Services	Timescale for investigation RCA templates
	10	August 2012 - Policy Committee Approval	Head of Governance and Legal Services	Minor amendments. Additional wording added to different sections of the policy relating to NHSLA standards following advice from assessor. This provides clarity to staff on how risks, incidents and trends are reviewed, analysed and monitored. Categorisation Matrix has been updated to reflect updates in policy timescales.
	10.1	March 13	Head of Governance and Legal Services	Minor amendments approved at Policy Committee on 1/3/13:Section 2 definitions – Add to definition of unexpected death 'where natural causes are not suspected' (NPSA 2010) Protocol 2 section 1.6 changed to cover all relevant NHS Cancer screening programmes. Update to audit table.
	11	July 13	Head of Governance	Review of Risk assessment form and

			and Legal Services	RCA tool, New subgroups established CLIP and Executive RCA sign off, amended ICO categorisation for serious and reportable IG incident, statement writing guidance added for staff.
	12	Feb 15	Healthcare Governance Manager/s	Review of Risk assessment form and RCA tool, New subgroups established CLIP and Executive RCA table top meeting, amended ICO categorisation for serious and reportable IG incident
	13	Sept 15	Head of Governance and Legal Services	Review in line with NHS England Serious Incident Framework March 2015
		Oct 15	Head of Governance and Legal Services	Addition of equipment reporting requirements.
	13.1	Jan 16	Head of Governance and Legal Services	Update to Attachment 2 RCA investigation report template
	13.2	March 16	Head of Governance and Legal Services	Update to procedure 2 re local checking and validation of catastrophic risk.
	14	April 17	Head of Governance and Legal Services	Annual Review
	15	June 18	Head of Governance and Legal Services	Annual Review (inc NE guidance 2018, CQC, HSE MoU etc)
	16	June 19	Head of	Annual review (inc

			Governance	revision of RCA template, add to definitions and RCA process.
	16.1	June 2020	Head of Governance	Director Sponsor approved extension until September 2020 whilst full review is undertaken.
	17	October 2020	Head of Governance	Full Review to include updates to National guidance, local processes, categorisation matrix and RCA templates.
	17.1	April 2021	Head of Governance	Key changes updated to the policy that takes effect prior to its annual review in September 21.
	17.2	Sept 2021	Head of Governance	The Cancer Screening programme QA recommendation for guidance reference is updated in Procedure 1 – section 1.16 and Protocol 2 – section 3.11. Coroner reporting guidelines is references in Procedure 1 section 3.5. Document and group name changes throughout.
	17.3	May 2022	Head of Governance	Extension applied
	17.4	September 2022	Deputy Director of Assurance	Extension applied
	17.5	April 2023	Deputy Director of Assurance	Extension applied
	17.6	October 2023	Deputy Director of Assurance	Inclusion of holding statement due to the implementation of OP04, Patient Safety

				Incident Response Policy

Intended Recipients: All staff have a responsibility for incident reporting and local risk management. Staff with supervisory and management responsibility must ensure they have adequate knowledge of the risk management and escalation processes contained within this policy.

Training and Dissemination: Please refer to OP41 for course availability, booking and frequency of training. Risk Management eTraining for senior and for all staff and is available electronically via the KITE site on Trust Intranet. RCA training is available via face to face sessions or via Microsoft Teams bookable via the Governance Department on 5114. Risk Assessment Training is a face to face sessions bookable via the Trust H&S Co-ordinator on 8125.

To be read in conjunction with: Specific policies referenced in the document.

Equality Impact [initial] Assessment [all policies]: **Completed Yes**

Full Equality Impact assessment [as required]: **Completed No**

If you require this document in an alternative format e.g., larger print please contact Central Governance Department on Ext 5114.

Consultation Group / Role titles and Date: Divisional Management, Executive Director/s, Governance Department (Risk management and Compliance), Policy Review Group.

Name of approving Trust level committee and Review Date	Trust Policy Group – September 2021 Endorsement by Sponsor and Chair of TPG – October 2023 – Version 17.6
Approving Body	Trust Management Committee – September 2021
Date of latest Issue	April 2023
Review Date and Frequency [standard review frequency is 3 yearly unless otherwise indicated]	October 2023 [annual review]
Contact for Review	Director of Assurance
Implementation plan / arrangements [Name implementation lead]	Deputy Director of Assurance
Monitoring arrangements and Committee	Annual Policy audit reported to the Quality and Safety Advisory Group (refer section 9 of policy)

Document summary / key issues covered:

Policy covers the requirements for reporting, escalation and management of incidents and risks. It identifies timescales for reporting and external agencies to be notified. It provides a standard categorisation matrix for the grading of incidents, risks, complaints and claims, and templates for investigations and risk assessments. The policy includes the requirements for reporting, investigation and management of serious and reportable incidents and support provided to staff involved.

VALIDITY STATEMENT

This document is due for review on the latest date shown above.
After this date, policy and process documents may become invalid.
The electronic copy of this document is the only version that is maintained. Printed copies may not be relied upon to contain the latest updates and amendments.

Ratification Assurance Statement

Name of document: Risk Management and Patient Safety Reporting Policy

Name of author: Maria Author Job Title: Head of Governance

I, the above named author confirm that:

• The Policy presented for ratification meet all legislative, best practice and other guidance issued and known to me at the time of development of the said document.

• I am not aware of any omissions to the said document, and I will bring to the attention of the Executive Director any information which may affect the validity of the document presented as soon as this becomes known.

• The document meets the requirements as outlined in the document entitled Governance of Trust-wide Strategy/Policy/Procedure/Guidelines and Local Procedure and Guidelines(OP01).

• The document meets the requirements of the NHSLA Risk Management Standards to achieve as a minimum level 2 compliance, where applicable.

• I have undertaken appropriate and thorough consultation on this document and I have detailed the names of those individuals who responded as part of the consultation within the document. I have also fed back to responders to the consultation on the changes made to the document following consultation.

• I will send the document and signed ratification checklist to the Policy Administrator for publication at my earliest opportunity following ratification.

• I will keep this document under review and ensure that it is reviewed prior to the review date.

Signature of Author:

Date: 28/8/20

Name of Person Ratifying this document:

Maria Arthur

Job Title: Head of Governance

Signature: 

To the person approving this document:

Please ensure this page has been completed correctly, then print, sign and email this page only to: The Policy Administrator

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and policy version OP10 v17	**Policy Title Risk Management and Patient Safety reporting policy**	
Reviewing Group	Policy Group	**Date reviewed:** June 19
Implementation lead: Print name and contact details		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.	NA	
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form	E training in place for all staff, for senior managers and Market place session at induction.	
Development of Forms, leaflets etc; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed	Material developed for induction is under regular review.	
Strategy / Policy / Procedure communication; Consider 1. Key communication messages from the policy / procedure, who to and how?	Policy update - SMB Process changes eg Duty of Candour, Risk register process communicated via follow up emails and AUB.	
Financial cost implementation Consider Business case development	None identified	
Other specific Policy issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation	None	

Categorisation Matrix (Reviewed September 2020)

The Royal Wolverhampton NHS Trust

This matrix is designed to assist you when you are grading incidents, complaints and risks for severity. By determining the hazard or consequence, and then the likelihood of recurrence, you are able to assign a grade - for example, 5x5, 3x3, 1x1, etc. Then, by using the colour-coded table, you can determine the severity - yellow, green, red or amber. Grading should be completed by the person reporting as soon as possible after the incident occurs – the department / area manager will then review the initial grading and amend if necessary

Step 1: What is the hazard / harm / consequence?

			Need to consider whether the incident falls within the categories of Serious Incident Requiring Investigation (SIRI), refer OP 10 protocol 2		
	1	2	3	4	5
DESCRIPTOR	Insignificant	Minor	Moderate	Major	Catastrophic
Injury / Ill health **Consider harm caused to patient. See opposite.	No injury.	Short term injury probably takes less than one month to resolve. RIDDOR reportable minor injury/ ill health	Semi-permanent injury, e.g., may take up to one year to resolve. RIDDOR reportable moderate injury / ill health	Permanent injury, e.g., loss of body part, misdiagnosis, permanent disability. RIDDOR reportable major injury / ill health	Death.
Objectives / projects	Insignificant cost increase / schedule slippage. Barely noticeable reduction in scope or quality.	<1% over budget . schedule slippage. Minor reduction in scope or quality.	1 – 5% over budget / schedule slippage. Reduction in scope or quality requiring client approval.	6 – 25% over budget / schedule slippage. Doesn't meet primary objectives.	>25% over budget. Doesn't meet primary objectives.
Patient and public experience / complaint	Unsatisfactory experience not directly related to patient care.	Unsatisfactory experience – readily resolvable. Incorrect patient identification – no adverse outcome.	Mismanagement of patient care – short-term consequences. Incorrect patient identification – short-term consequences. Consent issues – readily resolvable.	Mismanagement of patient care – long – term consequences. Incorrect patient identification – long-term consequences. Consent issues – incorrect treatment with long-term sequelae.	Totally unsatisfactory patient outcome or experience. Incorrect patient identification leading to death. Consent issues leading to death or permanent damage.
Claim potential	Locally resolved claim (includes losses and compensation)	Substantiated complaint peripheral to clinical care. Minor staff attitude problems Potential for litigation/settlement <£5K	Below excess claim. Substantiated complaint involving lack of appropriate care / serious staff attitude problems. Potential for litigation/settlement <£50K	Claim above excess level. Multiple substantiated complaints. External inquiry Potential for litigation/settlement <£500K	Multiple claims or single major claim. Potential for litigation/settlement >£500K
Service / business interruption	Loss / interruption > I hour.	Loss / interruption > 4 hours.	Loss / interruption > I day.	Loss / Interruption > 1 week.	Permanent loss of service / facility.
Staffing and competence	Short-term low staffing level temporarily reduces service quality (< 1 day).	Ongoing low staffing level reduces service quality.	Unsafe staffing level or competence (< 1 day).	Unsafe staffing level or competence (< 1 week).	Ongoing or critical unsafe staffing level or competence.
Business risk (EXECUTIVE USE ONLY)			Moderate business failure resulting in reorganisation across a service/ division. Moderate loss of income. Loss of a single service. All staff within a major service affected.	Major business failure affecting a major service. Major loss of income. Loss of major service. All staff within a major service affected.	Large scale business failure affecting care of all patients and employment of all staff. Trust auditors not able to provide Board Assurance. All services at risk. All staff at risk.
Financial	Small loss (< £500).	Moderate loss (> £500)	Loss > 0.005% of budget (> £10,000).	Loss > 0.05% of budget (>£100,000).	Loss > 1% of budget (£2,000,000).
Inspection / audit / NICE guidance	Minor recommendations. Minor noncompliance with standards.	Recommendations given. Noncompliance with minor standards OR compliance but no audit trail to demonstrate that objectives are being met (NICE etc.)	Challenging recommendations. Noncompliance with regulation standards OR less than 50% of objectives within standard are met.	Enforcement action. Critical report. Multiple challenging recommendations. Major noncompliance with core standards.	Prosecution. Zero rating. Severely critical report. Noncompliance with NHS standards due to no objectives/ targets being met (NICE etc.).
Adverse publicity / staff morale	Rumours (potential).	Local media – short-term interest. Minor effect on staff morale.	Local media – long term interest. Significant effect on staff morale.	National media > 3 days. Enquiries from MPs.	National media > 3 days. Ministerial. Secretary of State involvement.
Fire Safety / Security General security of Trust property or services ***N.B. All incidents of physical assault must be entered onto Datix within 48hrs***	Minor noncompliance with fire safety codes of practice that will not compromise staff and patient safety Security incident with no adverse outcome	Fire code noncompliance that as a consequence could compromise staff taking effective action in the event of fire Security incident managed locally. Theft or loss of Trust property value <£100. Controlled drug (CD) discrepancy (accounted for)	Significant fire risk or Fire code noncompliance that will compromise staff taking effective action in the event of fire Security incident leading to compromised patient or staff safety. Theft or loss of Trust property <£1000. CD discrepancy not accounted for.	Significant fire risk or serious breach of statutory legislation that could compromise life safety or render the Trust liable to prosecution Serious compromise of patient or staff safety. Theft or loss of Trust property <£20,000.	Significant fire risk that in the event of fire will compromise life safety Infant abduction. Theft or loss of Trust property £20,000 plus
Environmental impact	Minor noncompliance with standards. Minimal increase in environmental impact.	Noncompliance with minor standards. Minor increase in environmental impact.	Noncompliance with core standards. Significant increase in environmental impact.	Enforcement action. Major noncompliance with core standards. Unacceptable impact.	Prosecution. Severely critical report. Severe impact on environment.
Staff experience ***N.B. All incidents of physical assault must be entered onto Datix within 48 hours***	Theft / or damage of personal property < £50.	Minor verbal abuse. Theft / or damage of personal property < £150.	Serious verbal abuse / minor physical assault. Theft / or damage of personal property £150 plus.	Serious physical assault / major injury.	Serious physical assault leading to death.
Information Governance / I.T.	Minor breach of confidentiality – no adverse outcome. Unplanned loss of IT facilities < half day. Health records / documentation incident – no adverse outcome. Equivalent to IG calculator score = 0	Minor breach of confidentiality – readily resolvable. Unplanned loss of IT facilities < 1 day. Health records / documentation incident – readily resolvable. Equivalent to IG calculator score = 1	Moderate breach of confidentiality – complaint initiated / adverse local publicity. Health records / documentation incident – patient care affected with short-term consequence. Equivalent to IG calculator score = 2 and above	Serious breach of confidentiality – more than one person / sustained local publicity / serious complaint. Unplanned loss of IT facilities > 1 day but less than one week. Health records / documentation incident – patient care affected with moderate consequence. Equivalent to IG calculator score = 2 and above	Serious breach – large numbers / national publicity / risk of claims payment. Unplanned loss of IT facilities > 1 week. Health records / documentation incident – serious consequence. Equivalent to IG calculator score = 2 and above
Number of people affected	0 to 5	6 to 10	11 to 20	21 to 50	More than 50

Use the information from the incident form / risk assessment / complaint to decide which descriptor box from the first column is applicable. Then read across to establish how severe the consequences or hazards are. You may find that the incident / risk assessment / complaint has consequences which fit into more than one descriptor box - if this is the case, you should choose whichever gives the higher score between 1 and 5.

**Please consider level of harm below where injury or ill health applies

No harm: Impact prevented – patient safety incident that had the potential to cause harm but was prevented; or incident occurred but no harm was caused.

Low harm: patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons.

Moderate harm: patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons.

Moderate increase in treatment: An unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care)

Severe harm: A patient safety incident that appears to have resulted in permanent harm to one or more persons.

Permanent harm: Permanent lessening of bodily functions; including sensory, motor, physiological or intellectual (Directly related to the incident and not related to the natural course of a patient's illness or underlying condition)

Death: Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care.

Prolonged psychological harm: psychological harm which the service user has experienced or is likely to experience, for a continuous period of at least 28 days. Please note incidents of prolonged psychological harm must be entered as either moderate or severe harm on Datix dependent on the circumstances in each case.

NB: For patient safety incidents where moderate, severe harm, death or prolonged psychological harm is caused please refer to OP 60 Being Open Policy to apply The Duty of Candour.

Step 2: What is the likelihood of occurrence?

Use the table below to ascertain how likely or how often the hazard is to occur.

LEVEL	DESCRIPTOR	DESCRIPTION
5	Almost certain	Likely to occur on many occasions; a persistent risk (daily).
4	Likely	Will probably occur, however not a persistent risk (weekly).
3	Possible	May occur occasionally (monthly).
2	Unlikely	Not expected to occur, however could given the right circumstances (annually).
1	Rare	Not expected to occur (yearly / years).

Step 3: Assign a grade

Multiplying the consequence (1 to 5) with the likelihood of occurrence (1 to 5) will give you the grade, e.g. Consequence : Minor (2) x Likelihood : almost certain (5) = 10 Amber.

Step 4: Assign severity

Use the colour-coded table below to plot the severity, e.g., 5x5 = Red, 3x3 = Amber, 1x1 = Green.

Impact	No injury. Unsatisfactory experience, not directly related to patient care. Complaint findings had potential to cause harm but was prevented/not realised in this case. Complaint fully and easily resolved locally.	Unsatisfactory experience readily resolvable. Substantiated complaint peripheral to clinical care eg. Minor staff attitude. Substantiated findings required extra observation, minor treatment, caused minimal harm. Complaint fully and easily resolved locally.	Substantiated complaint, lack of appropriate care/serious staff attitude problems Mismanagement of patient care, short term consequences ie a moderate increase in treatment which caused significant but not permanent harm. Refer matrix for moderate harm definition. Complaint readily resolved with additional actions.	Substantiated complaint. Mis-management of patient care – long term/permanent consequences. Single or multiple substantiated complaints with long term/permanent consequences. Loss of body part; long term disability etc refer to matrix harm definitions. Complaint findings meets/ potential meets the serious incident criteria.	Substantiated complaint. Mis-management of patient care leading to or potentially leading to death refer to matrix harm definitions. Complaint findings meets/ potential meets the serious incident criteria
Likelihood	1 - Insignificant	2 - Minor	3 - Moderate	4 - Major	5 - Catastrophic
5 - Almost Certain	5	10	15	20	25
4 - Likely	4	8	12	16	20
3 - Possible	3	6	9	12	15
2 - Unlikely	2	4	6	8	10
1 - Rare	1	2	3	4	5

* All risks graded ≥**12** must be escalated to the appropriate line management for further action / escalation to TRR.

Step 5: What action needs to be taken now?

The table below gives a brief guide to what level of action is required once you have identified the severity of the incident / risk. For a detailed explanation of staff responsibilities for risk management, please refer to Trust policies: OP 10, Risk Management Reporting. Complaints Policy OP 08. The reporter must establish whether the incident is a serious incident (SI) requiring reporting and investigation as listed in protocol 2 of OP 10 policy. E.g never events, unexpected / avoidable deaths, serious harm, abuse.

	Person(s) responsible for investigation and level of management.	**Local processes for review and accountability.**	**Notify responsible person within**
GREEN	Line / department manager / local staff.	At least quarterly review of all green incidents, risks etc., by local Governance forum. Sharing of lessons learned amongst relevant staff. Actions taken and lessons must be updated on Datix.	5 working days (If SI 2 hours, max 1 working day)
YELLOW	Line / department manager / local staff.	At least quarterly review of all yellow incidents, risks etc., by local Governance forum. Sharing of lessons learned amongst relevant staff. Actions taken and lessons must be updated on Datix.	5 working days (If SI 2 hours, max 1 working day)
AMBER	Department manager / Head of Service or appointed investigator.	Review incidents and investigations at local Governance forum, agree action plan, and sharing of lessons learned. Amber incidents require investigation / enquiry and an action plan where not immediately resolvable. Amber risks scoring ≥12 must be escalated to the appropriate line management for action.*Consider SI review (review risks monthly)	3 working days. (If SI 2 hours, max 1 working day)
RED * For serious events which are likely to attract media attention, all those affected must be informed of the incident before the media are (refer to OP 10 Protocol 2, Serious Incident Procedures).	Department manager / Head of Service or appointed investigator.	Review incidents at local Governance forum, agree action plan, and sharing of lessons learned. Red Incidents require investigation / enquiry and an action plan where not immediately resolvable. All red risks scoring ≥12 and must be escalated to the appropriate line management for action. *SI – Local Dept / Service managers are responsible for ensuring the follow up and closure of RCA actions and for assurance on improvement (Review risks monthly).	2 hours, max 1 working day

Remember:

- All incident entries must be entered onto Datix within 5 working days.
- All incident entries must be updated onto Datix and closed, within 45 working days.
- Update of investigation findings, lessons, actions and documents must be uploaded on Datix within 45 days.
- Please refer to SI guidance in protocol 2 of OP 10 Risk Management Reporting Policy for serious and externally reported incidents.
- All SI to be reported to the service / line manager within 2 hours or at latest within 1 working day.
- All action plans must include the names of those responsible for any actions, timescales for implementation and review and evidence of achievement.
- All action plans should be monitored by local Governance forums, with further monitoring as indicated above.
- All formal complaints must be answered within 30 working days.
- For help, advice or guidance, please contact: The Central Governance Team ext. 5114.
- Managers are required to approve all reported incidents within 5 working days.

RCA Report v. XX

Datix:

STEIS:

Type Required	Approval	By who	Date
Level 1 (Concise) – 48hr report	**Directorate**		
Updated Level 1 report (only for use when investigation is being closed at the Level 1 stage)	**Division**		
	Executive Review		

Is the incident Externally Reportable:	**Yes / No** **If Yes, please identify:**	**Commissioner**	
		SHOT	
		ICO	
		MHRA	
		CQC	
		MHRA	
		HPA	
		Other	
Is this a Never Event?	**Yes/ No**		
STEIS category			

48 Hour Report Lead Investigator:
Once signed off by Directorate and Division please add dates and details of who has approved and forward final version to rwh-tr.SUIReporting@nhs.net

Level 1 (Concise) Investigation/ 48 Hour Report

Return the completed report to rwh-tr.SUIReporting@nhs.net by midday on the 2nd working day after the incident

- Refer to prompt cards listed in the guidance at the end of this template (and detailed in Appendix 2 OP10 to respond to questions asked by Commissioners for particular types of incidents.
- On completion ensure all guidance text (in green) is deleted.

Initial Findings

Incident description and consequences	
Incident description: [*e.g. A 47 year old female patient (Hospital/NHS number) with asthma sustained brain damage following IV administration of a drug to which she was known to be allergic.]*	
Outcome for patient/ person affected	
Outcome for patient/ affected person, and/or current condition.	
Datix no:	
Incident date:	*[Date of incident, or – if not known – date identified as an incident to the Trust]*
Incident type:	*[See Datix record]*
Directorate/ Specialty:	
Actual effect on patient:	*[Clarify effect (if any) on patient – this must also be described on Datix and categorized as: death, severe harm, moderate harm, low harm or no harm]*
Current status of patient:	*Clarify status of patient – this may be already included on Datix]*
Involvement and support of patient and/ or relatives	
[State if Duty of Candour/ Being Open has been implemented (or arrangements for implementation) and provide date and details. If this will not be implemented, please state rationale. *Duty of Candour = Patient (or representative(s) to be notified of incident and the fact that an investigation is taking place within **10 working days** of the incident.]* Has the family been involved in the investigation? Yes/No (If yes state how below) *State whether and how the patient or family has been consulted as part of this investigation or whether/how invited to express any concerns to be investigated.*	

Detection of incident
[Understanding as at 48 hours of the stage in the patient's treatment and the method by which the incident was identified.]
Action taken immediately
[State any actions or changes made immediately following the incident]
Relevant policies/ procedures
[Detail any relevant policies, procedures, protocols or guidelines that apply, e.g. national, Trustwide or local]
Identified issues
[Understanding as at 48 hours of the key problem points, expressed as care and service problems e.g. Nurses on the short stay ward failed to complete the section in the patient notes to highlight the existence of known allergies] State Prompt card utilised (if any)
Contributory Factors and Incidental Findings
[Understanding as at 48 hours of contributory factors – please refer to The Contributory Factors prompts listed in Level 2 template below]
Root Causes
[Understanding as at 48 hours of underlying causes of the incident – include rationalisation of this understanding]
Recommendations
[List of CLEAR NUMBERED recommendations which address the risk and reduce re-occurrence. These must be succinct not detailed [detail belongs in the action plan [Appendix 1]. Please also number the actions. Recommendations MUST address the root causes identified above. Please review tools available on NPSA website www.npsa.nhs.uk.rca 1. 2. 3. etc.
Lessons Learnt and shared learning
*Highlight any general learning from this incident or issues that have been identified. Describe what staff should be aware of or practice in light of the event eg when away on leave staff must handover urgent tests to an appropriate colleague to check results. This could include any examples of good practice identified. The learning should take into consideration how to address behaviours that are contributing and preventing safe systems/practice.*1. 2. 3. **Arrangements for shared learning (including scope of sharing and person responsible):** 1. 2. 3.

Name and Job Title of Author/ 48 Hour Report Lead
Add text here
Names and Job Titles of individuals involved in the investigation (including those interviewed and from whom statements have been obtained) – PLEASE ENSURE THAT STATEMENTS ARE REQUESTED ***N.B. NAMES WILL BE REDACTED FROM FINAL VERSION***
Add text here
Date of report
Add text here

RCA Guidance

RCA 'Key Questions' – Prompt Cards – for investigator reference please remove this list in final RCA report

PC1 – Abscond
PC 2 – Accident whilst in Hospital
PC 3 – Admission of a under 16 or under 18 in Mental Health
PC 4 – Allegation against Healthcare professional or non professional PC 5 – Assault
PC 6 – Bogus Healthcare workers PC 7 – Chemical Incident
PC 8 – Child Abuse PC 9 – Child Death PC 10 – Child Injury
PC 11 – Communicable Disease and infection issue (refer also protocol 2 for specific investigation guidance) PC 12 – Confidential Information leak (refer also protocol 2 for ICO checklist)
PC 13 – Delayed Diagnosis PC 14 – Drug Incident
PC 15 – Failure to act on test results PC 16 – Failure to obtain consent
PC 17 – Fire – accidental or non accidental PC 18 – Homicide/attempted suicide
PC 19 – Hospital Medical Equipment Failure PC 20 – Maternity incidents
PC 21 – Pressure Ulcers (refer also protocol 2 for specific investigation guidance)
PC 22 – Radiology Incidents
PC 23 – Scanning Incidents
PC 24 – Safeguarding Vulnerable Adults/Child PC 25 – Screening Issues
PC 26 – Serious self-inflicted injury/Attempted suicide PC 27 – Slips/Trips/Falls
PC 28 – Sub-optimal care of the deteriorating patient PC 29 – Suicide
PC 30 – Surgical error
PC 31 – Unexpected death
PC 32 – VTE (refer also protocol 2 for specific investigation guidance)
PC 33 – Wrong site surgery
PC 34 - Error & Mistake Classification Considerations & Questions
PC 35 - Behaviour – Common Clinical Bias Considerations & Questions

*For **Level 1 (Concise)/ 48 Hour Report** and **Level 2 (Comprehensive)/ RCA** Investigations*

For support see '**Types of Preventative Actions Planned'** – tool at www.npsa.nhs.uk/rca

Please note: The final action plan will be approved by the Divisional Management Team before sending onto the Commissioners for closure. The Healthcare Governance Manager will ensure that the Directorate Management Team receives the finalised version of the report and action plan. The Directorate will then be responsible for ensuring the Implementation Leads are aware of the action attributed to them and the target date for the action to be completed and monitoring all actions through to completion.

No	Root Cause	Recommendation to address identified root cause/s (and human factors)	Action/s to implement the recommendation	Implementation Lead (Job Title)	Target Date for Completion	State evidence of the completed action
1						
2						
3						
4						
5						

RCA Report v.X

Draft/Final

*delete as appropriate

Datix:

STEIS:

Type Required	Approval	By who	Date
Level 2 (Comprehensive)	Directorate		
	Division		
	Executive Review		

Is the incident Externally Reportable:	Yes / No If Yes, please identify:	Commissioner	
		SHOT	
		ICO	
		MHRA	
		CQC	
		MHRA	
		HPA	
		Other	
Is this a Never Event?	Yes/ No		
STEIS category			

48 Hour Report Lead Investigator:
Once signed off by Directorate and Division please add dates and details of who has approved and forward final version to rwh-tr.SUIReporting@nhs.net

Level 2 (Comprehensive) Investigation/ RCA Report

- Refer to prompt cards listed in the guidance at the end of this template (and detailed in Appendix 2 OP10 to respond to questions asked by Commissioners for particular types of incidents.
- On completion ensure all guidance text (in green) is deleted.

Investigation Scope/ Terms of Reference

To be agreed by RCA Lead and Divisional Lead prior to investigation

Scope of timeline (incl. any limitation)	Acute secondary care time frames usually span at least the period of admission to incident occurrence, though there will be occasions where the pre-treatment period needs to be included. Community based incidents, or where multiple agencies are involved, or if there is any uncertainty at all about where the 'ball started to roll', usually start with the incident and map the chain of events backwards until there is enough information.
Questions to be addressed via this investigation:	
Staff (job titles or teams) to be asked for comments/ interviewed	These names are not exhaustive as new information might necessitate new interviews
People/ teams/ specialists to be invited to Table Top Review	
Family concerns identified to be investigated.	The lead undertaking Duty or Candour and/or the investigator is to involve the patient/relative/carer in the investigation to the extent they would wish and must identify here any concerns raised by the family to form part of the investigation.

Timeline of events/ chronology

Date/ time	**Event** e.g. rather than only a list of observations, consider also telling the reader whether the observations taken were stable for the patient, or that the results indicated the patient had a higher than normal heart rate and low blood pressure. e.g. rather than only stating the risk assessment was completed, consider highlighting what the risk assessment advised (no action/action required).	**Source/s of evidence**

Contributory Factors

Contributory findings/ factors make the event more likely or the harm more severe, and so play a part in causing or influencing the incident. Even if they are not the root cause and don't have a clear solution they must be recorded below. Authors must aim to identify any 'Human Factors' involved. Where Human factors, human error or behavioral influences are identified please be sure to complete the error classification and behavioral influences below to ensure there is appropriate understanding is the affecting issues and for action planning. (Incidental findings or observations can be recorded under lessons learnt and shared learning where these are relevant to improve outcomes or reduce recurrence).

	Component(s)
Individual (e.g. physical, psychological, social, personality issues, fatigue, stress, hunger, anger/ frustration)	
Team & Social (e.g. role congruence, leadership, support and cultural factors including whether it was an ad hoc team or formed team, whether there a was a brief/ debrief)	
Communication (e.g. verbal, written, non-verbal communication)	
Task (e.g. guidelines, procedures, policies, decision making aids)	
Education & Training (e.g. competence, supervision, availability, appropriateness)	
Equipment & Resource (e.g. displays, integrity, positioning, usability, availability, 'making-do', standardisation)	
Working Conditions (e.g. administrative, physical environment, staging, work load, time pressure (real or perceived)	
Organisational/Strategic (e.g. organisational structure, priorities, safety culture, any learning from previous similar incidents / near miss?)	
Patient (e.g. clinical condition, mental / psychological, physical, interpersonal)	

Error classification and Behavioural influences

Where human error is identified the investigator must seek to identify the type of error, the level of mistake [Rasmussen & Reason] and where possible any identifiable behavior influences at play [Kahneman]. The type and level of error (mistake) can be concluded from the situation, the physical evidence gathered and any behavior influence from the context of staff statements, investigation interviews etc. By identifying these factors, it provides a wider understanding for learning across the trust.

Error type classification (Prompt Card 34)

Classification	Comment
Skill Error	
Rule Error	
Knowledge Error	

Error level Classification (Prompt Card 34)

Classification	Comment
Slip, lapse, distraction –	
Unintended Mistake-	
Intended Decision -	
Violation **–** (Reasoned Clinical Judgment)	
Violation **–** (Reckless or Malicious Behaviour requiring just culture or other agency considerations)	

Behaviour Influences (Prompt Card 35) – *To apply learning especially where reflection may be required you need, on a balance of probability to understand how behavior influenced the journey of decision making.*

Behavioural Influences	Identify which apply to the incident circumstances (with rationale). Then follow the prompts for action planning.
Attitude, Clinicians are subject to two common biases - anchoring (fixating on the first visual/verbal cue available) and availability bias (dependence on information that is readily available) and they influence an immediate sense of what is going on, if they go unrecognised they are difficult to eliminate. **Prompts for action planning:** • Increased importance and awareness of decision making • Promote critical thinking • Can processes enforce a system constraint	
Attention – Our attention narrows when under stress or fatigue and can be catastrophic in	

medical situations. Attention failure further affects decision making, when under pressure it is difficult to pay attention to everything that is going on, we narrow our focus and attention -Tunneling, Selectivity bias, attentional biases can have catastrophic consequences. **Prompts for action planning:** • Raise awareness of conditions which may compromise decision making (fatigue, sleep deprivation, cognitive overload) • Review resources • Limit Overcrowding • Wider ergonomic considerations	
Cognition - Cognitive biases influence the way we think and can lead to errors in decisions and judgement – a tendency to make mental shortcuts -thinking fast and slow, it's impossible to be 100% right all the time. There are many common and consistent biases some of which particularly affect medical decision making, for example, Confirmation bias (looking for information to support your view), frequency gambling (expecting the presenting condition to be the one that most commonly reflects the symptoms seen, expectation bias (expectations about an outcome influence perceptions of one's own or others' behaviour), outcome bias (evaluating the outcome of a decision when the outcome is already known), hindsight bias (overestimate the ability to have predicted an outcome that could not possibly have been predicted). **Prompts for action planning:** • Increased awareness of the importance of decision making • Training in cognitive bias • Promote metacognition, mindfulness and reflection • Promote critical thinking • Teach cognitive debiasing	.

Identifying the Root cause - Use the 5 Why questions to drill down to a root cause/s. The final why is usually the Root Cause but root cause/s can emerge sooner. There are generally a number of contributory causes to consider, the investigator must seek to identify the fundamental and underlying root cause/s.

What *should* have happened (consider policy, clinical guidelines, accepted practice)	**What *actually* happened** (what was the variation from expected events)?	**Reason for variation** Identify the relevant factors to explore and ask yourself the 5 WHYs, this will help to identify the root cause of the variation.
Doctor should have marked the site for minor invasive procedure	*Doctor did not mark the site resulting in treating the wrong side*	*Why 1. Protocol for site marking in minor invasive procedures not followed;* *Why 2. Local Policies and Protocols not well understood or used* *Why 3. Local policy is at variance with routine practice hence custom and practice is relied on which varies between practitioner.*
Staff should have followed the massive haemorrhage guideline	Patient deteriorated without escalation.	Why 1. Staff did not perceive/judge the appropriate level of risk. Why 2. The patient seemed stable and alert in spite of high pulse rate and low BP. Why 3. There was a delayed and unexpected reaction to the patient's blood loss which was not detected. Why 4. The patient had mental health issues to which their agitation was attributed. Why 5. Staff did not fully review the ambulance record which would have indicated the volume of blood loss at home and alerted to the potential patient risk.

What controls or barriers will be used to prevent the incident happening again?

Root Cause	Existing Controls/Barriers	Did the Barrier work? Y/N	If no why not?	Lessons Learned
Please include all root causes		*Assess the effectiveness of the barrier*		

Datix number:
STEIS number:
STEIS category:
What happened?
Brief factual summary of the incident.
What was the impact or outcome for patient?
Outcome for patient/ affected person, and/or current condition.
How was the patient involved in the investigation?
Duty of Candour or Being Open. Did the patient/relatives have any queries or concerns to be addressed as part of the investigation? Was the patient/relatives interviewed? Has the family been involved in the investigation? Yes/No (If yes state how below) *State whether and how the patient or family has been consulted as part of this investigation or whether/how invited to express any concerns to be investigated.*
What problems were identified?
e.g. omissions, failed barriers, care or service delivery problems. Where human factors featured, how did any suspected/known behavior influences contribute to the journey of decision making? State Prompt card utilised (if any)
Why did it happen? (Root Causes identified using '5 whys')
These are the most fundamental underlying Factors that led to the incident. They must be addressed or escalated. Root causes must be explicitly described so in completing below please identify how these factors directly contributed to the event or the outcome occurring (not vague list e.g. "communication failure") 1. 2. 3. etc.
What should we do to address the root causes? (Recommendations)
Recommendations must be numbered and be directly cross-referenced to the identified root cause(s) to reduce risk or prevent reoccurrence. They must be clear but not detailed (detail belongs in the action plan) and needs to focus on what changes and actions are recommended to reduce the risk of this happening again. To ensure effective and focused action, recommendations must be kept to a minimum where ever possible. 1. 2. 3. etc.

Lessons Learnt and Shared Learning
Highlight any general learning from this incident or issues that have been identified. Describe what staff should be aware of or practice in light of the event eg when away on leave staff must handover urgent tests to an appropriate colleague to check results. This could include any examples of good practice identified. The learning should take into consideration how to address behaviours that are contributing and preventing safe systems/practice.
Lessons 1. 2. 3. **Arrangements for shared learning (including scope of sharing and person responsible):** 1. 2. 3.
RCA Lead Investigator Name and Job Title
Joint/ Second Investigator Name and Job Title (if applicable)
Report version number / date
Names and Job Titles of individuals involved in the investigation (including those interviewed and from whom statements have been obtained) NB. Investigation interviews must be conducted in accordance with interview guidance below. ***N.B. NAMES WILL BE REDACTED FROM FINAL VERSION***
Table Top Scrutiny Meeting Attendees (Names and Job Titles) ***N.B. NAMES WILL BE REDACTED FROM FINAL VERSION***
What Information gathered:

Eg. Witness statements from:
Interview records for:
Staff rotas
CCTV
Equipment maintenance records
Audit data
Site visit (photographs)
Expert opinion on patient outcome/treatment
Specialist website on best practice
Professional practice information
Patient medical record including investigation results and communication letters
Trust Policy/SOP for:
Review of lessons learned and actions taken following previous incidents
Prompt card utilised (if any)
Limitations of report:
Eg. The investigation was unable to access the patient's GP records
It was not possible to interview staff X due to ….

RCA Guidance

RCA 'Key Questions' – Prompt Cards – for investigator reference please remove this list in final RCA report

PC1 – Abscond
PC 2 – Accident whilst in Hospital
PC 3 – Admission of a under 16 or under 18 in Mental Health
PC 4 – Allegation against Healthcare professional or non professional PC 5 – Assault
PC 6 – Bogus Healthcare workers PC 7 – Chemical Incident
PC 8 – Child Abuse PC 9 – Child Death PC 10 – Child Injury
PC 11 – Communicable Disease and infection issue (refer also protocol 2 for specific investigation guidance) PC 12 – Confidential Information leak (refer also protocol 2 for ICO checklist)
PC 13 – Delayed Diagnosis PC 14 – Drug Incident
PC 15 – Failure to act on test results PC 16 – Failure to obtain consent
PC 17 – Fire – accidental or non accidental PC 18 – Homicide/attempted suicide
PC 19 – Hospital Medical Equipment Failure PC 20 – Maternity incidents
PC 21 – Pressure Ulcers (refer also protocol 2 for specific investigation guidance) PC 22 – Radiology Incidents
PC 23 – Scanning Incidents
PC 24 – Safeguarding Vulnerable Adults/Child PC 25 – Screening Issues
PC 26 – Serious self-inflicted injury/Attempted suicide PC 27 – Slips/Trips/Falls
PC 28 – Sub-optimal care of the deteriorating patient PC 29 – Suicide
PC 30 – Surgical error
PC 31 – Unexpected death
PC 32 – VTE (refer also protocol 2 for specific investigation guidance)
PC 33 – Wrong site surgery
PC 34 - Error & Mistake Classification Considerations & Questions
PC 35 - Behaviour – Common Clinical Bias Considerations & Questions

Guidance for conducting an Investigation interview

Persons invited to an investigation interview will be informed of/that:

- The purpose of the interview, details of the incident being investigated and reinforced that the SUI investigation is not part of a disciplinary process.
- In the event of legal/human resource proceedings or on request of patient or the Coroner, the incident investigation report and supporting statements may be released with personal details redacted (where appropriate).
- The time, place and length of the interview.
- Who will be conducting the interview (and any others present).
- Any documentary evidence available to them during the interview.
- The fact that they can bring a friend or colleague (NB confidentiality in their involvement).
- The fact that notes will be taken to inform the investigation but these will not act as a formal witness statement. Formal witness statements will be requested separately/in addition to the meeting.
- Investigation interview meetings notes and the information conveyed must be shared with interviewed persons to confirm accuracy and for consideration with signed statement/s. Both the interview notes and formal statements can be requested in a court of law.

General Guidance on Statement writing

- Write clearly (using black ink) or have it typed
- State full name, Job title, how long in post
- Answer the specific request not what you think it is or feel it must be.
- Refer to the medical records in chronological order
- Explain in brackets any unusual terms
- Deal with facts not opinion unless asked to do so
- Do not comment on actions of others
- Write in first person (e.g. I, me)
- Use page numberings 1 of 3, 2 of 3 etc, sign and date the end of each page
- It must be in your own words and express what you wish to say and not what anyone else says you must say
- Contact Legal Services Manager(s) for help and advice
- List all documents referenced in your statement e.g. case notes, policies, national standards etc.
- Check statement for accuracy, relevance, clear and concise language

Action Plan Template

Please note: The final action plan will be approved by the Divisional Management Team before sending onto the Commissioners for closure. The Healthcare Governance Manager will ensure that the Directorate Management Team receives the finalised version of the report and action plan. The Directorate will then be responsible for ensuring the Implementation Leads are aware of the action attributed to them and the target date for the action to be completed and monitoring all actions through to completion.

No	Root Cause	Recommendation to address identified root cause/s (and human factors)	Action/s to implement the recommendation	Implementation Lead (Job Title)	Target Date for Completion	State evidence of the completed action
	Copy directly from Executive Summary	*Copy directly from Executive Summary*				State target level of completion e.g. 80% of staff trained, 100% of equipment replaced. Measurement of effectiveness.
1						
2						
3						
4						

NB All above actions must be discussed with the implementation lead and any resources eg Finance, staff time for training etc identified for agreement within the action.

RCA 'Key Questions' – Prompt Cards

PC1 – Abscond
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PC 33 – Wrong site surgery
PC 34 - Error & Mistake Classification Considerations & Questions
PC 35 - Behaviour – Common Clinical Bias Considerations & Questions

Abscond – 'Key Questions' – Prompt Card (PC1)

At time of reporting	Prior to closing incident
What happens within the incident – establish timeline?	Have there been similar absconding incidents in that area?
Was the patient known to be an absconding risk before this incident?	If YES, had the previous root causes been adequately addressed and any changes embedded into practice?
If YES, did they have an appropriate care plan in place?	Had clinical staff received relevant training in respect to reducing the risks of missing patients?
What level of observation was in place at the time of the incident, and was this appropriate given the patients known absconding history?	Was the Missing Patient Policy utilised effectively within this incident?
Was observation being delivered in accordance with agreed best practice?	Has the Missing Patient Policy been revised or amended following this incident?
Were the appropriate individuals notified that the patient had gone missing?	Has the patient been asked why they absconded?
Has the patient returned?	Have the lessons learnt from this incident been shared appropriately?
How was the patient on return?	
Was the level of observation increased when the patient returned?	
Has the route that the patient used to abscond been identified?	
Was this exit point alarmed?	
If NOT, have the appropriate controls now been put in place to reduce the risks of reoccurrence?	
Did this incident take place at a known high risk time e.g. shift handover, mealtime, drug round etc?	
Has a post-incident debrief taken place?	
What section of the Mental Health Act was the patient detained patients?	
Is local practice in respect to reducing incidents of missing patients in line with best practice?	
Is the abscond reportable to the Care Quality Commission?	

Accident Whilst in Hospital – 'Key Questions' – Prompt Card (PC2)

At time of reporting	Prior to closing incident
What was the nature of the accident?	Could this accident have been foreseen?
What happened within the incident – establish timeline?	Have there been any similar incidents within the area?
Who was affected by this incident?	If YES, had the previous root cause been adequately addressed?
What was the nature and extent of injuries?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Did this incident involve any hospital equipment?	If YES, has these changes been embedded into practice?
If YES, what was the model, make and serial number?	Have the lessons learnt from this incident been shared and actioned appropriately to reduce/prevent re-occurrence?
Have there been any national alerts issued in respect to this equipment?	
Is the incident RIDDOR reportable?	
What controls have been put into place post-incident to reduce the risks of reoccurrence?	

Admission of an under 16 or under 18 in Mental Health – 'Key Questions' – Prompt Card (PC3)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Had staff involved in the incident received appropriate safeguarding training?
Why was admission to hospital necessary?	Had staff involved in the incident received appropriate training in respect to the management of an under 18 admission?
Were all efforts made to secure an age-appropriate bed prior to admission?	Has the service got a policy in place concerning the admission of under 18s to adult mental health in-patient facilities?
What level of observation has the young person been placed on?	If YES, was this policy followed?
What measures have been put into place to ensure that the young person receives age-appropriate care and treatment?	Have the lessons learnt from this incident been shared appropriately?
What was the young persons' reaction to admission?	
Has the Care Quality Commission been notified of admission in accordance with CQC guidance?	
Did the young person have appropriate contact from CAMHS during their admission to hospital?	
Was the local Safeguarding Lead informed of the admission to hospital?	

Allegation against HC Professional or Non Professional – 'Key Questions' – Prompt Card (PC4)

At time of reporting	Prior to closing incident
What happened within the incident– establish timeline?	Had staff involved in the incident received appropriate safeguarding training?
What is the nature of the allegation that has been made against the healthcare worker?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
What controls have been put into place to protect patients?	Have there been any similar incidents within the area?
What controls have been put into place to support other team members affected by this incident?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Has the healthcare worker been suspended from duties?	If YES, has these changes been embedded into practice?
If NOT what controls have been put into place to safeguard others during the period of investigation?	Have the lessons learnt from this incident been shared appropriately?
Is there any Police involvement?	
Has a decision been made in respect to informing the relevant professional bodies (As appropriate)?	

Assault – 'Key Questions' – Prompt Card (PC5)

At time of reporting	Prior to closing incident
What happened within the incident– establish timeline?	Had staff involved in the incident received and appropriate training in the prevention and management of violence and aggression?
What was the nature of the assault?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
What was the nature and extent of injuries?	Have there been any similar incidents within the area?
Who was affected by this incident?	If YES, had the previous root causes been adequately addressed?
Did the alleged perpetrator have a known history of aggressive behaviors and/or threats to others?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
If YES, was this information known before the incident?	If YES, has these changes been embedded into practice?
Is there any Police involvement?	Have the lessons learnt from this incident been shared appropriately?
If YES, have charges been brought against the alleged perpetrator?	
Has the local Security Management Specialist been informed of this incident?	
Was the local Security Management Specialist actively involved in the incident investigation?	
Did this incident involve the use of a weapon?	
If YES, was this removed from the alleged perpetrator?	
Has post-incident debriefing taken place?	

Bogus Health Workers – 'Key Questions' – Prompt Card (PC6)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
How was the service alerted to this incident?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Did the bogus health worker manage to gain access to any patients?	If YES, has these changes been embedded into practice?
If YES, have patients concerned been informed?	If YES, had the previous root causes been adequately addressed?
Did the bogus health worker manage to gain access to any patient identifiable data?	Have the lessons learnt from this incident been shared appropriately?
If YES, have patients concerned been informed?	
Have the Police been informed of this incident?	
If YES, what actions have been taken?	
Is it clear how the bogus health worker managed to access the service?	

Chemical Incident – 'Key Questions' – Prompt Card (PC7)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
What was the nature of the incident – chemical involved?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
What are the known risks of exposure to this chemical?	If YES, has these changes been embedded into practice?
Have any staff/patients/visitors been affected by this incident?	If YES, had the previous root causes been adequately addressed?
If YES, what is the extent of their exposure and how will this affect them in the short and long term?	Have the lessons learnt from this incident been shared appropriately?
Have any clinical areas been closed as a result of this incident?	
If YES, what measures have been put into place to ensure service continuity?	
Has the local Health & Safety Officer reviewed this incident?	

Child Abuse – 'Key Questions' – Prompt Card (PC8)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Had staff involved in the incident received appropriate safeguarding training?
What was the nature of the abuse?	Are there any other individuals who may be at risk e.g. other siblings or a parent in an abusive relationship?
How long has the child been at risk?	If YES, what actions have been taken to safeguard these individuals from potential or further abuse?
What contact has the child had with health and social care services?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
Were the actual or potential risks of abuse known prior to this incident?	Have there been any similar incidents within the area?
If YES, what controls were in place to protect the child – and why did they fail?	If YES, had the previous root causes been adequately addressed?
Has the local Safeguarding Lead been informed of the incident?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Was the local Safeguarding Lead actively involved in the incident investigation?	If YES, has these changes been embedded into practice?
Where is the child now – how are they being supported and cared for?	Was this case subject to a Serious Case Review?
Where is the alleged perpetrator – what action(s) have been taken against them?	If YES, what were the findings?
Have the Police been informed about the incident?	Have the lessons learnt from this incident been shared appropriately?
If YES, what actions have been taken?	
Will this case be subject to a Serious Case Review?	

Child Death – 'Key Questions' – Prompt Card (PC9)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Was the local Safeguarding Lead actively involved in the incident investigation?
How did the child die – document cause of death once known?	Had staff involved in the incident received appropriate safeguarding training?
Were there any safeguarding concerns?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
If YES, what controls were in place to protect the child – and why did they fail?	Have there been any similar incidents within the area?
What contact has the child had with health and social care services?	If YES, had the previous root causes been adequately addressed?
Will the death be subject to a Serious Case Review?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
If YES, what was the outcome of this Serious Case Review?	If YES, has these changes been embedded into practice?
Has the local Safeguarding Lead been informed of this incident?	Was this death referred to the Child Death Overview Panel (CDOP)?
Has this death been referred to the Child Death Overview Panel (CDOP)?	If YES, what were the findings?
Was this an unexpected death?	Have the lessons learnt from this incident been shared appropriately?
If the death was unexpected – what made it so?	

Child Injury – 'Key Questions' – Prompt Card (PC10)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Had staff involved in the incident received appropriate safeguarding training?
What was the nature of the injury?	Has this incident identified any areas that need to be changed within policies/procedures/guidance
Was this injury accidental or non-accidental in nature?	If YES, has these changes been embedded into practice?
What was the cause of the injury?	Have the lessons learnt from this incident been shared appropriately?
What has been the impact of this injury on the child?	
Are there any safeguarding concerns?	
If YES, what actions have been taken?	
Are there any other individuals who may be at risk e.g. other siblings or a parent in an abusive relationship?	
If YES, what actions have been taken to safeguard these individuals?	

Communicable Disease and Infection Issue – 'Key Questions' – Prompt Card (PC11)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Have there been any similar incidents within the area?
What is the nature of the communicable disease or infection control incident?	If YES, had the previous root causes been adequately addressed?
Who has been affected by this – patients, staff, visitors etc.?	Has the local Infection Control Committee been advised of the incident and the outcome of the root cause analysis?
What measures have been taken to reduce risks of cross infection?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Has the local Infection Prevention and Control Lead been informed of this incident?	If YES, has these changes been embedded into practice?
Was the local Infection Prevention and Control Lead actively involved in the incident investigation?	Have the lessons learnt from this incident been shared appropriately?
Have any clinical areas been closed as a result of this incident?	
If YES, what measures have been put into place to ensure service continuity?	
What controls have been put into place post-incident to reduce the risks of reoccurrence?	
Where appropriate, have other internal/external agencies been notified e.g. HPA, PCT, mandatory surveillance systems, communications etc.?	
Has the incident been escalated via all appropriate internal pathways e.g. Serious Incident reporting and HCAI reporting?	

Confidential Information Leak – 'Key Questions' – Prompt Card (PC12) – refer also to Information Commissioner Checklist in Protocol 2

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
What is the nature of the confidential information leak theft, accidental loss, inappropriate disclosure, procedural failure etc. ?	Have there been any similar incidents within the area?
What type of information has been lost? –paper/ electronic/ sensitivity of information involved	If YES, had the previous root causes been adequately addressed?
Who is affected by this loss (include how many actual/potential persons), and have they been informed?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Has the local Information Governance Lead been informed of this incident?	If YES, has these changes been embedded into practice?
Was the local Information Governance Lead actively involved in the incident investigation?	Have the lessons learnt from this incident been shared appropriately?
Has the Caldicott Guardian been informed of this incident?	
How many records were involved?	
Has the level of the Information lost within this incident been rated in accordance with the Department of Health guidance "Checklist for Reporting", Managing and Investigating Information Governance Serious Untoward Incidents" and what was the outcome of the scoring?	
In the event that the incident has been rated as a Level 2 or above, has the organisation informed the Information Commissioner?	
Does the loss of this information loss potentially impact onto any vulnerable groups?	

Delayed Diagnosis – 'Key Questions' – Prompt Card (PC13)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Have there been any similar incidents within the area?
Why was the diagnosis delayed?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
How was the patient affected by this delay in the diagnosis?	If YES, had the previous root causes been adequately addressed?
Has the patient been informed of the fact that their diagnosis was delayed?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
If YES, how have they reacted to this?	If YES, has these changes been embedded into practice?
Has the organisation taken measures to confirm whether any other patients have experienced similar delay?	Have the lessons learnt from this incident been shared appropriately?

Drug Incident – 'Key Questions' – Prompt Card (PC14)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Was the local Medicines Management Lead actively involved in the investigation?
What was the nature of the drug incident?	Has the root cause of this incident been identified?
What should the patient have received – and what did they actually receive?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
What were the consequences to the patient of this drug error?	Have there been any similar incidents within the area?
Did they require additional treatment or therapy?	If YES, had the previous root causes been adequately addressed?
Has the patient been informed about the drug error?	Has the local Medicines Management Committee been advised of the incident and the outcome of the root cause analysis?
YES, how have they reacted to this?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Did this incident take place during a protected drug round?	If YES, has these changes been embedded into practice?
Did this incident involve a drug that was not normally used within that clinical environment?	Have the lessons learnt from this incident been shared appropriately?
Was this incident identified as a Never Event?	
If YES, did a level 2 incident investigation take place?	
Has the local Medicines Management Lead been informed of this incident	
In the event that the incident involved a Controlled Drug has the designated responsible Officer and the Controlled Drug local intelligence Network been informed?	

Failure to act upon test results – 'Key Questions' – Prompt Card (PC15)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Was this monitoring effective in alerting staff to the failure to act upon test results?
How did the service become aware of this incident?	Has the root cause of this incident been identified?
What were the test results that staff failed to act upon?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
What were the consequences to the patient of this incident?	Has the organisation taken measures to identify whether any other patients who may have had their test results missed?
Did the patient require additional treatment or therapy?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Has the patient been informed of this incident?	If YES, has these changes been embedded into practice?
If YES, what was their reaction?	Have the lessons learnt from this incident been shared appropriately?
What type of monitoring was in place for the patient at the time of the incident?	

Failure to obtain consent – 'Key Questions' – Prompt Card (PC16)

At time of reporting	Prior to closing incident
What happened within the incident– establish timeline?	What systems are in place within the organisation for ensuring best practice in respect to gaining consent?
What is the normal procedure for consent within the organisation?	Had staff involved in this incident received appropriate consent training?
What level of consent must have been obtained?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
What factors contributed to the failure to obtain consent?	If YES, has these changes been embedded into practice?
Was this consent written or oral?	Have the lessons learnt from this incident been shared appropriately?
Had the patients' mental capacity been assessed?	
Was the patient considered to be vulnerable?	
If YES, has the local Safeguarding Lead been informed of this incident?	
If YES, what was their reaction?	
Has national guidance been following in respect to Consent?	

Fire – accidental or non-accidental – 'Key Questions' – Prompt Card (PC17)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Have individuals affected by this incident received appropriate post-incident support/debriefing?
How did the fire impact onto patients and the service?	Had staff involved in this incident received appropriate fire training?
Was anyone injured?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
If YES, what was the nature and degree of the injuries sustained?	If YES, has these changes been embedded into practice?
Was there any property damage?	Have the lessons learnt from this incident been shared appropriately?
If YES, what was the nature and degree of the damage sustained?	
Have any clinical areas been closed as a result of this incident?	
If YES, what measures have been put into place to ensure service continuity?	
Has the cause of the fire been identified?	
Has the local Fire Safety Officer been informed of this incident?	
Was the Emergency Response to the fire appropriate?	
In the event of alleged Arson, have the Police been informed?	
If YES, what actions have been taken?	

Homicide/Attempted Homicide – 'Key Questions' – Prompt Card (PC18)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	What is the current status of any legal proceedings?
Is the alleged perpetrator known to mental health services?	What is the outcome of the Court Case? – verdict and sentence
If YES, when did they last have contact with mental health services?	Is there a need to undertake an independent inquiry into the circumstances of this case?
Has the incident been reported in accorded with Department of Health guidance "Independent investigation of adverse events in mental health services"	Have the lessons learnt from this incident been shared appropriately?
Is there any indication that this may be a Domestic Homicide?	
If YES, has the incident been managed in accordance with the Home Office guidance "Domestic Homicide Review – Statutory Guidance for the conduct of Domestic Homicide Reviews"	
Are the Police involved?	
If YES, what actions have taken place?	
Has the alleged perpetrator been formally charged with an offence?	
Have individuals affected by this incident received appropriate post-incident support/debriefing?	

Please note that a Homicide cannot be closed on STEIS until such time as:

- **The decision is taken that an independent inquiry is not required OR the independent inquiry has been completed.**

Hospital Medical equipment failure – 'Key Questions' – Prompt Card (PC19)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Had staff involved in the incident received appropriate training in the use of the piece of Hospital/Medical equipment?
What was the actual piece of hospital or medical equipment that failed?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
If YES, what were the model, make and serial number and has the MHRA been informed?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Have there been any national alerts issued in respect to this equipment?	If YES, has these changes been embedded into practice?
What arrangements were in place to ensure appropriate monitoring/servicing/recalibration of this Hospital/Medical equipment?	Have the lessons learnt from this incident been shared appropriately?
Had this monitoring/servicing/recalibration been taken in accordance with the manufactures guidance?	
Was anyone injured as a direct result of this incident?	
If YES, what was their reaction?	
Is the incident RIDDOR reportable?	
Did this Hospital/Medical equipment failure lead to any delays in treatment or suspensions of service?	
If YES, what measures have been put into place to ensure service continuity?	
Has the organisation undertaken a check of all similar equipment to ensure that it is working effectively?	

Maternity Incidents – 'Key Questions' – Prompt Card (PC20)

At time of reporting	Prior to closing incident
What happened within the incident – intrapartum death, intrauterine death, maternal death, Maternal unplanned admission to ICCU, suspension of maternity services, unexpected admission to NICU (neonatal intensive care unit) or unexpected neonatal death?	If a Supervisory Investigation took place, what was the outcome?
What happened within the incident? – establish timeline	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
What happened to the mother? What happened to the baby?	If YES, has these changes been embedded into practice?
What was the gestational age of the baby?	Have any training issues with individuals been addressed?
Did the mother and/or baby have any known risk factors prior to the incident?	Have the lessons learnt from this incident been shared appropriately?
What are the short term and long term implications of this incident?	
Was the incident a Never Event?	
If appropriate, had the appropriate WHO Surgical Safety Checklist been used during this procedure?*	
Has the mother/family been informed of this incident?	
Was there appropriate staffing at the time of the incident?	
If YES, what was their reaction?	
Has post incident debriefing and support been offered? – for staff/patient/family	
Was there appropriate staffing at the time of the incident?	
Is there a Supervisory Investigation also taking place?	
Had staff involved in the incident received appropriate training in the use of the equipment used in this incident?	
Has consideration been given to whether the practice of any individual has been found to be below agreed professional standards?	

Pressure Ulcer – 'Key Questions' – Prompt Card (PC21)

At time of reporting	Prior to closing incident
What events lead to the development/identification of the pressure ulcer (establish timeline) ?	Have root causes been identified?
Was appropriate assessment carried out?	Had staff involved in the incident received appropriate training in respect to pressure ulcer prevention and management?
Were care bundles in place & used?	Was there appropriate access to pressure relieving measures in a timely manner?
Have safeguarding issues been considered?	If NO, what actions have been taken to ensure a more timely response in the future?
In cases where concordance issues may exist has mental capacity been confirmed?	What systems are in place within the organisation to reduce the risks of pressure ulcer formation and deterioration?
Is there evidence of referral to Tissue Viability Services?	How regularly are these systems audited to ensure best practice standards are being adhered to?
Is the TV Nurse involved in the investigation?	Has this incident identified any areas that need to be changed within policies/procedures/guidance
Was the pressure ulcer considered avoidable or non-avoidable?	If YES, has these changes been embedded into practice?
Was the best practice followed in respect to pressure ulcer care?	Have the lessons learnt from this incident been shared appropriately?

Radiology Incidents – 'Key Questions' – Prompt Card (PC22)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Has the organisation undertaken a look back exercise to assure themselves that no other patients have been affected by a similar incident?
What procedure was being undertaken?	Had staff involved in the incident received appropriate training in the procedure they were performing in this incident?
What dose of radiation should the patient have received?	Had staff involved in the incident received appropriate training in the use of equipment used in this incident?
What dose did the patient actually receive?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
What was the planned location (target area) of the radiation & what did the patient receive?	If YES, has these changes been embedded into practice?
What are the short term and long term implications of this error?	Have the lessons learnt from this incident been shared appropriately?
Had the appropriate WHO Surgical Safety Checklist been used during this procedure?	
Has the patient been informed of this incident?	
If YES, what was their reaction?	
Was the error caused by Hospital/Medical equipment failure?	
If YES, what were the model, make and serial number?	
In the event that there was a Hospital/Medical equipment failure, what measures have been put into place to ensure service continuity?	
Has the organisation undertaken a check of all similar equipment to ensure that it is working effectively?	

Scanning Incidents – 'Key Questions' – Prompt Card (PC23)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Has the organisation undertaken a check of all similar equipment to ensure that it is working effectively?
What procedure was being undertaken?	Has the organisation undertaken a look back exercise to assure themselves that no other patients have affected by a similar incident?
What scan must the patient have received?	Had staff involved in the incident received appropriate training in the procedure they were performing in this incident?
What scan did the patient actually receive?	Had staff involved in the incident received appropriate training in the use of equipment used in this incident?
What was the planned location (target area) of the radiation & what did the patient receive?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
What are the short term and long term implications of this error?	If YES, has these changes been embedded into practice?
Has the patient been informed of this incident?	Have the lessons learnt from this incident been shared appropriately?
If YES, what was their reaction?	
Was the error caused by Hospital/Medical equipment failure?	
If YES, what were the model, make and serial number?	
In the event that there was a Hospital/Medical equipment failure, what measures have been put into place to ensure service continuity?	

Safeguarding Vulnerable Adult or Child – 'Key Questions' – Prompt Card (PC24)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Has the suspected staff perpetrator been reported to Designated Adult Safeguarding Manager and process for DBS followed?
What was the nature of the safeguarding concerns?	Had staff involved in the incident received appropriate safeguarding training?
How long has the individual been at risk?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
What contact has the patient had with health and social care services?	Have there been any similar incidents within the area?
Were the actual or potential risks of abuse or neglect known prior to this incident?	If YES, had the previous root causes been adequately addressed?
If YES, what controls were in place to protect the patient – and why did they fail?	Has this incident identified any areas that need to be changed within policies/procedures/guidance
Was there a strategy meeting with the Police &/or Social Care at time of incident?	If YES, has these changes been embedded into practice?
Has the local Safeguarding Lead/Team been involved in the incident investigation?	Have the lessons learnt from this incident been shared appropriately?
Where is the patient now – how are they being supported and cared for?	
Where is the alleged perpetrator – what action(s) have been taken against them?	
Have the Police been informed of this incident?	
If YES, what actions have been taken?	
Are these individuals who may be at risk e.g. other patients within the care area, other family members?	
If YES, what actions have been taken to safeguard these individuals from potential or further abuse?	
Are there any concerns in respect to Mental Capacity?	
Are there any concerns in respect to Deprivation of Liberty Safeguards (DoLS)?	

Screening Issues – 'Key Questions' – Prompt Card (PC25)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Was this error caused by a failure in communication e.g. patient not receiving a call for screening?
What was the screening procedure that was being undertaken?	If YES, what changes have been put into place to improve communication systems?
What must the patient have received?	Had staff involved in the incident received appropriate training in the use of the equipment used in this incident?
What did the patient actually receive?	Has this incident identified and areas that need to be changed within policies/procedures/guidance?
What are the short term and long term implications of this error?	If YES, has these changes been imbedded into practice?
Has the patient been informed of this incident?	Have the lessons learnt from this incident been shared appropriately?
If YES, what was their reaction?	
Was the error caused by Hospital/Medical equipment failure?	
If YES, what were the model, make and serial number & have the manufacturer and MHRA been contacted?	
In the event that there was a Hospital/Medical equipment failure, what measures have been put into place to ensure service continuity?	
Has the organisation undertaken a check of all similar equipment to ensure that it is working effectively?	
Has the organisation taken measures to determine whether any other patients have been affected by a similar incident?	

Serious Self Inflicted Injury/Attempted Suicide – 'Key Questions' – Prompt Card (PC26)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Have there been any similar incidents within the area?
What was the nature of the injury sustained by the patient?	If YES, had the previous root causes been adequately addressed?
What are the short term and long term implications of this injury?	Had staff involved in the incident received appropriate training in suicide prevention?
How did the patient gain access to the item(s) that they had harmed themselves with?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Was this patient known to be at risk of self-inflicted injury before this injury?	If YES, has these changes been embedded into practice?
If YES, what controls had been put into place to reduce risks?	Have the lessons learnt from this incident been shared appropriately?
What level of observation was in place at the time of the incident, and was this appropriate given the patients known risks of self-inflicted injury?	
Has the patient been asked why they injured themselves?	
Has the level of intent been identified?	
Is the patient in regular contact with Mental Health Services?	
Did this incident take place at a known high risk time e.g. shift handover, mealtime, drug round etc?	
Was the incident an attempted hanging within an in-patient setting?	
If YES, when was the last environmental ligature risk assessment undertaken?	
Were the appropriate anti-ligature measures in place e.g. collapsible rails etc.?	
Have individuals affected by this incident received appropriate post-incident support/debriefing?	

Slips/Trips/Falls – 'Key Questions' – Prompt Card (PC27)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Had staff involved in the incident received appropriate training in falls prevention?
What was the nature of the accident?	Is the incident RIDDOR reportable?
What was the nature and extent of injuries?	Have there been any similar incidents within the area?
Who was affected by this incident?	If YES, had the previous root causes been adequately addressed?
Was this patient known to be at risk of falls before this incident?	Could this fall have been foreseen?
If YES, what controls had been put into place to reduce risks? Was the 'post falls care' correctly followed (including initial and subsequent neurological observations?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
What level of observation was in place at the time of the incident, and was this appropriate given the patients known risks of falls?	If YES, has these changes been embedded into practice?
Was appropriate falls reduction equipment in place?	Have the lessons learnt from this incident been shared appropriately?

Sub-optimal care of the deteriorating patient – 'Key Questions' – Prompt Card (PC28)

At time of reporting	Prior to closing incident
What happened within the incident– establish timeline?	Has the root cause of this incident been identified?
How did the service become aware of this incident?	What controls have been put into place post-incident to reduce the risks of reoccurrence?
What were the consequences to the patient of this incident?	Have there been any similar incidents within the area?
Did the patient require additional treatment or therapy?	If YES, had the previous root causes been adequately addressed
What type of monitoring was in place for the patient at the time of the incident?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Was this monitoring effective in alerting staff to the deteriorating patient?	If YES, has these changes been embedded into practice?
Has the patient/family been informed of this incident in line with Being Open principles?	Have the lessons learnt from this incident been shared appropriately?
If YES, what was their reaction?	

Suicide – 'Key Questions' – Prompt Card (PC29)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Have there been any similar incidents within the area?
What was the method and cause of death?	If YES, had the previous root causes been adequately addressed?
Was this patient known to be at risk of suicide before this incident?	Had staff involved in the incident received appropriate training in suicide prevention?
If YES, what controls had been put into place to reduce risks?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
What level of observation was in place at the time of the incident, and was this appropriate given the patients known risks of suicide?	If YES, has these changes been embedded into practice?
Have individuals affected by this incident received appropriate post-incident support/debriefing?	Have the lessons learnt from this incident been shared appropriately?
Was this an in-patient suicide?	
If YES, is this a Never Event?	

Surgical Error – 'Key Questions' – Prompt Card (PC30)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Has the organisation undertaken a check of all similar equipment to ensure that it is working effectively?
What surgical procedure was being undertaken?	Has the organisation undertaken a look back exercise to assure them that no other patients have affected by a similar incident?
What was the nature of the error which occurred?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
What were the consequences to the patient of this incident?	Have any training issues with individuals been addressed?
What are the short term and long term implications of this error?	If YES, have these changes been embedded into practice?
Had the appropriate WHO Surgical Safety Checklist been used during this procedure?	Have the lessons learnt from this incident been shared appropriately?
Was this incident identified as a Never Event?	
If YES, did a level 2 incident investigation take place?	
Had staff involved in the incident received appropriate training in the procedure they were performing in this incident?	
Had staff involved in the incident received appropriate training in the use of the equipment used in this incident?	
Has consideration been given to whether the practice of any individual has been found to be below agreed professional standards?	
Has the patient been informed of this incident?	
If YES, what was their reaction?	
Have individuals affected by this incident received appropriate post-incident support/debriefing?	
Was the error caused by Hospital/Medical equipment failure?	
If YES, what were the model, make and serial number?	
In the event that there was a Hospital/Medical equipment failure, what measures have been put into place to ensure service continuity?	

Unexpected Death – 'Key Questions' – Prompt Card (PC31)

At time of reporting	Prior to closing incident
What happened within the incident– establish timeline?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
What was the cause of death?	If YES, has these changes been embedded into practice?
Why was the death unexpected?	Was there a Coroners' Inquest?
Have individuals affected by this incident received appropriate post-incident support/debriefing?	If YES, what was the outcome of this Coroners' Inquest?
Will the death be subject to a Coroners' Inquest?	Have the lessons learnt from this incident been shared appropriately?

Venous Thromboembolism (VTE) – 'Key Questions' – Prompt Card (PC32)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Had staff involved in the incident received appropriate VTE training
What were the consequences to the patient of this incident?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
Was the patient assessed as being at risk of VTE prior to the incident occurring?	If YES, has these changes been embedded into practice?
If YES, was this VTE risk assessment undertaken utilising the Department of Health national VTE risk assessment tool?	Have the lessons learnt from this incident been shared appropriately?
Was the patient informed about the risks/complications of thromboprophylaxis?	
Had the patient received appropriate VTE prophylaxis in accordance with NICE guidance?	
What are the current systems within the organisation for checking that patient have had their risk of VTE assessed and appropriate Venous Thromboembolism prophylaxis provided?	
Was the patient provided with anti-embolism stockings prior to this incident?	
Did the patient have these stockings fitted and monitored in accordance with NICE guidance?	
Has the patient been informed of this incident?	
If YES, what was their reaction?	

Wrong Site Surgery – 'Key Questions' – Prompt Card (PC33)

At time of reporting	Prior to closing incident
What happened within the incident – establish timeline?	Have individuals affected by this incident received appropriate post-incident support/debriefing?
What surgical procedure was being undertaken?	Had staff involved in the incident received appropriate training in the procedure they were performing in this incident?
What site must have been operated on?	Has this incident identified any areas that need to be changed within policies/procedures/guidance?
What site was operated on?	If YES, has these changes been embedded into practice?
What were the consequences to the patient of this incident?	Have the lessons learnt from this incident been shared appropriately/
What are the short term and long term implications of this error?	
Had the appropriate WHO Surgical Safety Checklist been used during this procedure?	
Was this incident identified as a Never Event?	
If YES, did a level 2 incident investigation take place?	
Was this incident a wrong-side peripheral nerve block?	
If YES, had staff followed the Stop Before You Block guidance?	
Has the patient been informed of this incident?	
If YES, what was their reaction?	

Error & Mistake Classification Considerations & Questions" - Prompt Card (PC - 34)

Lines of inquiry to establish at investigation	Focus of redress action
*Identify as far as possible the **type of error** involved from the following classifications, more than one error type could be applied but consider the most relevant*	Are the circumstances such that you agree with the type of error identified
Skill Error – Often knowledge is present within the individual/team concerned, the question can be asked, the answer recorded but a mental slip, a lapse in concentration will lead to error.	Considerations for learning may have been as a result of tiredness, stress hunger, issues in their own personal life, consider reflection, system change or individual staff support. Often not prevented by training, discipline or policy as no one is resistant to interruptions, tiredness or fatigue. • Human-centered design (consistency e.g. up always means off; intuitive layout of controls and instrumentation; level of automation etc.) • Checklists and reminders; procedures with 'place markers' (tick off each step) • Independent cross-check of critical tasks • Removal of distractions and interruptions • Sufficient time available to complete task • Warnings and alarms to help detect errors • Often made by experienced, highly-trained, well-motivated staff: A**dditional training not valid**
Rule Error – This is the mistaken application of a rule or policy in place, or a disregard to the same for whatever reason. If identified the question below applies, was it intended or unintended. If behaviour is based on remembered rules and procedures, mistake occurs due to mis-application of a good rule or application of a bad rule: • Ignore alarm in real emergency, following history of spurious alarms	Considerations for learning though training or just culture if a violation of a rule (https://improvement.nhs.uk/resources/just-culture-guide/) • Plan for all relevant 'what ifs' (procedures for upset, abnormal and emergency scenarios) • Regular drills/exercises for upsets/emergencies • Clear overview / mental model (clear displays; system feedback; effective shift handover etc.) • Diagnostic tools and decision-making aids (flowcharts; schematics; job-aids etc.) • Competence (knowledge and understanding of system; training in decision-making techniques) • Organisational learning (capture and share experience of unusual events)

Knowledge Error – This is a failure to recognise a lack of knowledge e.g. undertaking a task outside of their skill sets, again this would need consideration of intended or unintended below. It could also be because of a lack of training, individually or corporately. • Individual has no rules or routines available to handle an unusual situation: • Resorts to first principles and experience to solve problem: • Rely on out-of-date pathway to plan unfamiliar route • Misdiagnose process upset and take inappropriate corrective action (due to lack of experience or insufficient / incorrect information etc.)	Considerations for learning through training or just culture if undertaking tasks outside their skill set it could be considered as a violation depending upon the circumstances (https://improvement.nhs.uk/resources/just-culture-guide/) • Plan for all relevant 'what ifs' (procedures for upset, abnormal and emergency scenarios) • Regular drills/exercises for upsets/emergencies • Clear overview / mental model (clear displays; system feedback; effective shift handover etc.) • Diagnostic tools and decision-making aids (flowcharts; schematics; job-aids etc.) • Competence (knowledge and understanding of system; training in decision-making techniques) • Organisational learning (capture and share experience of unusual events)
Now we have considered the error we need to classify the level of mistake involved from the following classifications.	Are the circumstances such that you agree with the type of mistake identified
Slip, lapse, distraction – usually as a result of stress, fatigue and environmental factors and can occur at any time. Usually a skill error, losing a sense of what was going on momentarily a loss of situational awareness but not leading to further cognitive based errors and unintended mistakes. <u>SLIP -COMMISSION</u> • A simple, frequently-performed physical action goes wrong: • Move a switch up rather than down (wrong action on right object) • Take reading from wrong instrument (right action on wrong object) • **Transpose digits during data input into a process control interface** <u>LAPSE -OMISSION</u> Short-term memory lapse; omit to perform a required action:	What was going on? What's the significance? Has it led to or contributed to further errors?

• Medical implement left in patient after surgery • Miss crucial step, or lose place, in a safety-critical procedure	
Unintended Mistake- this can be either skill, rule or knowledge but it will likely to have been influenced by cognitive biases and situational awareness. To obtain a wider understanding on how bias influences behavior and motivation you should now refer to PC-35	Where identified how can behaviour influences be addressed are system constraints possible?
Intended Decision -Intended is rare but it can be because of a clinical judgment that had to be undertaken and whilst it may be a violation of a rule (policy/procedure), or whilst a lack of knowledge was present the circumstances demanded an immediate response, it must be considered further as to the reason behind the judgement (violation below)	Considerations for learning
Routine, Situational and Exceptional Violation – Whilst a violation in the circumstances it was reasonable and can be identified as a reasoned Clinical Judgment	**Routine Violation** – Non-compliance becomes the 'norm'; general consensus that rules no longer apply; characterised by a lack of meaningful enforcement of constraints: **Situational Violation** – Non-compliance dictated by situation-specific factors (time pressure; workload; unsuitable tools & equipment; weather); non-compliance may be the only solution to an impossible task: **Exceptional Violation –** Person attempts to solve problem in highly unusual circumstances (often if something has gone wrong); takes a calculated risk in breaking rules:
Violation – Reckless or Malicious Behaviour requiring just culture or other agency considerations	Follow standard procedures for the involvement of other agencies or recommend within the report that ESERG consider recommendations for a just culture approach (https://improvement.nhs.uk/resources/just-culture-guide/)

Behavior – "Common Clinical Bias Considerations & Questions" -Prompt Card (PC -35)

Lines of inquiry to establish at investigation (and potential questioning)	Focus of redress action
Attitudinal Bias – Anchoring Bias "A tendency to fixate upon the first verbal or visual cue, healthcare staff may then find it difficult to move away once anchored"	We are all subject to anchoring and once anchored it is difficult to shift, these are common biases in healthcare
How was the patient presenting, did this affect initial decision making? Did anyone challenge this approach? If so, did the member of staff re-evaluate?	Remember attitudinal bias tends to set people up to making further errors of attention and cognition
Attitudinal Bias -Availability Bias "A tendency to depend upon information that was readily available or springs easily to mind"	If not anchored by an opening comment or visual cue this common phenomenon of availability bias may be involved
What information did the individual rely upon? Was new or other information available to them? Did other members of staff alert them to other information? If so, did the member of staff re-evaluate?	***Have you identified an attitudinal bias, often the beginning of the decision-making journey?*** • Understand the importance and awareness of decision making • Has critical thinking been applied? • Consider what processes may be needed to enforce a system constraint
Attentional Bias -Tunneling-In a stressful situation attention narrows and may focus on a specific task to the exclusion of processing any other information-It helps to prevent you from being overwhelmed but prevents the assimilation of new or unexpected information. You focus on a channel of perception e.g. only looking or listening	When working under pressure we are subject to attention bias and we then lose focus on what is going on around us and narrow our focus on getting a task done, sometimes referred to as task fixed.
How busy was the individual/unit that day? What does it mean in terms of patient numbers, breaches and staffing, vacancy or sickness? Could this have influenced decision making?	Whilst bias is often identified from the context of the investigation, the situational (factual) evidence will set the ground to understanding the context within which an individual/team were functioning in
Attentional Bias -Selectivity "Similar to tunnelling but may have a more psychological element. They may select information to focus on because of negative or positive psychological associations. E.g. focusing physical symptoms because of a sense of weakness or hopelessness in being able to manage a coexisting psychological condition or of confronting embarrassing symptoms	Attentional bias in healthcare can be catastrophic, it is unusual for attention and attitude not to be present but not impossible.
Similar to tunneling above but now consider any final decision that was made and how any final cognitive bias affected decision making	***Within the attention area of behaviour influence how, if at all, has attentional bias affected further the decision making?***

	• Have you identified conditions which may have compromised decision making (fatigue, sleep deprivation? cognitive overload) • How have resources, patient numbers + breaches influenced attention • Are there wider ergonomic considerations
Cognitive Bias - Conformation Bias "A tendency to look for evidence that confirms or matches the current situation or assessment, this bias restricts the assimilation of new information needed to accurately update the situation	There are many types of cognitive bias in healthcare and they are the final decision for poor judgment, we can't get it right 100% of the time. See 50 Cognitive Bias in medicine by Pat Croskerry (internet search) for more information.
Cognitive Bias - Frequency Gambling – At moments of diagnostic uncertainty it is natural to assume a presenting condition may be the most frequently occurring with those symptoms; however this may not necessarily be accurate.	Kahneman provides a wider explanation of the psychology behind these biases, humans utilise a dual cognitive process to solve problems\make decisions – fast intuitive, automatic, emotional (system 1) and slow, methodical and logical (system 2) and both are valid.
Cognitive Bias-Expectation Bias – "A tendency to weigh the importance of information based upon its expected value due to its origin rather than upon its own merits"	The problem is system 1 (fast) is easier to do particularly when tired or bored or working with repetition. We cannot change the fact that humans find it easier to think fast but we can anticipate and plan for cognitive failures and embed greater safety in our systems.
Cognitive Bias -Outcome Bias- A tendency to judge the value of a decision based upon its outcome rather than the decision-making process involved	***Have we identified the final decision-making error? In terms of any personal reflection understand the full decision-making journey through attitude-attention-cognition (AAC).*** • Have you identified the journey of decision making across AAC? • Have those involved received training in dealing with cognitive bias? • Were there missed opportunities for metacognition, mindfulness and reflection e.g. questions raised by nursing staff which were ignored or not considered?

The Royal Wolverhampton NHS
NHS Trust

Datix No:
Risk Ref: _____

OP10 Attachment 3

Refer to the guidance before completing and use a separate form for each risk. After completing Sections A-C please give this form to your manager. Thank you.

SECTION A: Initial Assessment Details		
Date of Assessment:		**Risk Assessor(s):**
Directorate / Specialty:		
Location:		

SECTION B: The Risk
Provide a description of the local hazard, problem or concern (potential dangers / harm of risk): identified from your service activity or the trigger lists provided in HS01 Management of Health & Safety Policy. Trigger lists are available for: Workplace, Manual Handling, COSHH, DSE, Work Equipment and Slips, Trips & Falls. (Trigger lists MUST be used as per HS01, Attach Risk Assessment to trigger sheet where applicable) Fire Risk Assessments have a specific form please refer to HS26 Fire Policy – these will be undertaken by the Fire Management Team. Who is affected? What is the potential outcome(s)?
How was the risk identified

Control Measures in Place	Responsible/Lead for Control	Date Started	Gaps in Controls

The Royal Wolverhampton NHS
NHS Trust

Initial Risk Evaluation with controls: (Please use the Trust Categorisation Matrix and circle below)				
Likelihood: 1 2 3 4 5	*Consequence:* 1 2 3 4 5	*Severity:* (1- 3) green	(4 – 6) yellow	(8 – 12) amber	(15+) red

SECTION C: Treatment Plan (Further measures required to reduce the risk)				
Action No	Action Required	Responsible/Lead for implementation	Timescale for completion (**MUST** have date, **NOT** on-going)	Date Action Complete

SECTION D: To be completed by the areas Lead Manager for Risk / Head Nurse.				
Risk Re-Evaluation after Action(s) Implemented: (Please use the Trust Categorisation Matrix and circle below) i.e. the target risk score once actions are in place				
Likelihood: 1 2 3 4 5	*Consequence:* 1 2 3 4 5	*Severity:* (1- 3) green	(4 – 6) yellow	(8 – 12) amber	(15+) red

Recommended actions in Section C are agreed and I have added as necessary			
Full Name:		**Designation:**	
Signature:		**Date:**	

Date for Review:	

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NHS Trust

SECTION E: RISK ASSESSMENT REVIEW SHEET

Treatment Plan (Further measures required to reduce the risk)								
Date of Review	Actions required/brought forward from last review (state action numbers)	Changes to/or new controls	Grade	Responsible / Lead for Implementation of Action	Timescale for Completion	Date Action Complete	Managers Signature for RA & Actions	Comments (Barriers / Progress)

Next Review Date :

Date of Review	Actions required/brought forward from last review (state action numbers)	Changes to/or new controls	Grade	Responsible / Lead for Implementation of Action	Timescale for Completion	Date Action Complete	Managers Signature for RA & Actions	Comments (Barriers / Progress)

Next Review Date :

Date of Review	Actions required/brought forward from last review (state action numbers)	Changes to/or new controls	Grade	Responsible / Lead for Implementation of Action	Timescale for Completion	Date Action Complete	Managers Signature for RA & Actions	Comments (Barriers / Progress)

Next Review Date :

This form is to be used by those who have the responsibility and have had training to undertake risk assessments. A new form must be completed for each new risk identified. All sections of this form are mandatory.

SECTION A: Assessment Details

Date of Assessment: The date the assessment was undertaken.

Directorate/Specialty: The directorate/specialty that the risk assessment is being conducted by or on behalf of.

Location: The exact location that the risk assessment is focused on, where applicable.

Risk Assessor(s): Please list the name(s) and job title(s) of all people involved in producing the risk assessment.

SECTION B: The Risk

Hazard, Problem or Concern: A hazard is any substance, process, action, inaction and/or object that could have a consequence, which may cause danger or harm to an individual, be it staff, patient, visitor or other; or damage to property or equipment.

It is important to remember that hazards may be many and varied within your area of work.

- Staff shortages
- Manual handling
- Trailing leads
- Poor office environment
- Poor access
- Insufficient equipment

Use the trigger lists/pre-assessment forms referred to in HS01 to assist with identifying the hazards associated with your service.

A hazard could have a number of potential outcomes. Therefore identify the potential consequence, danger or harm that the identified hazard may cause. A hazardous process can be broken down into its component parts, each of which will have its own danger. Having identified the dangers, you can now assess the risk for each identified danger.

How was risk identified: Please indicate from what source the risk has been identified e.g.

- ✓ In-house specialist knowledge.
- ✓ Incidents / complaints / claims.
- ✓ Internal / external audit / assurance reports
- ✓ Business Plan

Include details of the identified Underlying Causes.

Control Measures already in place: Please list all controls that are *already* in place to reduce the identified risk.

Description: A description of the control identified.

Responsible/Lead: The individual responsible for the identified control, include job title.

Date Started: When was the control started.

Gap in Controls: Any identified barriers encountered when trying to perform the identified control. Or an indication that the control is failing to achieve its objective.

Initial Risk Evaluation: This is the initial assessment of risk with the control(s) in place. To assist in scoring the risk please use the Trust's Categorisation Matrix that has been provided to all areas in wall-chart format. Using the descriptors given identify the hazard/consequence and likelihood of occurrence. The combination of these will give you a severity grade which indicates the priority of the risk.

Please circle the likelihood, consequence and severity attributed.

When scoring the risk please do not go for the worst case scenario, the aim of a risk assessment is to identify what is reasonably likely to occur and how often.

SECTION C: Treatment Plan

Now that the consequence, danger or harm and the likelihood of occurrence have been identified, action to eliminate or reduce the risks needs to be identified.

The aim of any action in the first instance, if possible, is to eliminate the risk entirely. Thereafter the aim will be to reduce the risk to it's lowest.

Actions should be SMART and have objectives:

- ✓ Specific;
- ✓ Measurable;
- ✓ Agreed;
- ✓ Realistic;
- ✓ Time bounded

Actions need to be in place to reduce both likelihood and consequence.

Treatment Plan: All fields are mandatory for each action identified.

Action Required: A description of the action identified, including what objective the action will achieve.
Responsible/Lead: A person must be empowered to undertake and be responsible for the identified action, include job title.

Timescale for Completion: When the action has been identified it must be given a realistic date for commencement and completion. The greater the risk the sooner the start and completion date.

SECTION D: To be completed by Manager

A Senior Manager within the area of work must sign to agree the actions and risk scoring. They should also use their knowledge to complete and supplement the Treatment Plan identified in Section C.

Risk Ref: Located in the top left-hand corner. Please number each risk assessment with your own unique identification; this will make it easier for you to identify your assessments.

Date for Review: This should be no greater than 12 months

Risk Re-Evaluation: What will the risk score be (i.e.target score) when all of the identified actions have been completed. Ideally this should be lower than the previous score.

SECTION E: Risk Assessment Review Sheet

This section is to be used each time you review and monitor your risk assessment and must be completed following your Governance meeting discussion.

Once completed please send this risk assessment to your Line Manager for review and for consideration.

TO BE READ BEFORE FOLLOWING THIS POLICY

OP10 Risk Management and Patient Safety Reporting Policy

From 1 November 2023 this policy commences a phase out period, the guidance and principles of the NHS England Serious Incident Framework (2015) were used to write the OP10 Risk Management and Patient Safety Reporting Policy.
The National Patient Safety Strategy is introducing new ways of working in relation to patient safety incidents and investigations under the new Patient Safety Incident Response Framework (PSIRF).

The OP10 Risk Management and Patient Safety Reporting Policy will be replaced once these changes are fully implemented by the Trust.
The change from the Serious Incident Framework 2015 to PSIRF *does not* apply to incidents outside the scope of PSIRF (i.e., incidents not involving a patient), including incidents that relate to:

- Professional standards
- Information governance;
- Health and Safety incidents (that do not highlight a significant patient safety concern);
- Digital and IT;
- Financial investigations;
- Estates and facilities;

These will continue to be managed the way they are now.
The transition from the OP10 Risk Management and Patient Safety Reporting Policy to OP04 Patient Safety Incident Response Policy will commence on 1 November 2023 and is expected to take 3 - 6 months.
Serious incidents occurring before 1 November 2023 will be investigated and closed under the Serious Incident framework (2015), this will then conclude the period of policy overlap.

In summary
Serious Incidents reported prior to 1 November 2023 will continue to be managed under the serious incident framework (2015).

Patient safety incidents reported on or after 1 November 2023 will be managed using the PSIRF Policy.
Reference to both policies for processing should be made accordingly.

1.0 Incident Reporting and Monitoring

1.1 Any member of staff – including temporary, agency, locum or contractors – can report an incident or near miss. In addition, students and others on placement, visitors and patients are able to report incidents; in this way the Trust demonstrates that it actively encourages open and honest disclosure in the interests of safety and quality improvement.

1.2 All incidents or near miss events will be reported using the Trust Incident Report Form, which is available either electronically (via Datix web) on the intranet or in paper booklet format. Guidance on completion is provided with both formats.

1.3 Incidents or near misses must be reported as soon as they are identified. The Trust sets out standards within which it expects incidents to be reported and entered onto Datix within step 5 of the Categorisation Matrix (Attachment 1).

1.4 Occasionally an incident will not be identified as such at the time of its occurrence. In these cases an incident report must be completed as soon as the incident has been recognised regardless of the interval since its occurrence.

1.5 All staff are encouraged to attempt an initial grading of the incident by using the Categorisation Matrix (Attachment 1).

1.6 All reported incidents must be signed off and the grading validated as soon as possible (within a maximum of 5 working days) by the person in charge of the area at the time of reporting. Where paper forms are used as a backup system the top (white) copy is submitted to the appropriate person for inputting onto Datix and the pink copy is retained locally for reference. After inputting, the white copy of the form is forwarded to the Governance Department for retention centrally.

1.7 All areas will review reported incidents at their local governance meetings. Detail summaries are reviewed for red and amber incidents (including STEIS reportable incidents). Incidents graded yellow and green are reviewed via trends monitoring and by local managers for individual redress and closure. The minutes of local governance meetings and manager liaison will ensure that all staff have access to feedback from incidents reported (see also Governance and Risk Management Framework). Managers can also provide feedback via the Datix system and must do so where this is requested.

1.8 All incidents meeting the criteria of a SUI will be reported to the Trust Directors and Commissioners.

1.9 All Information Governance (IG) incidents that are logged via Datix will be scored using either the IG SI calculator in Protocol 2 (table 2a) or the IG Cyber Calculator in Protocol 2 table 2b. All IG incidents scoring level 2 or above will be considered against the SI categories and will be reported to local Commissioners if they meet the SI criteria. Following the RCA, all level 2 or above incidents will be escalated to Caldicott/ SIRO for consideration for reporting HSCIC/ ICO.

1.10 All IG Incidents regardless of the level will be scored to assess the level of severity in line with Protocol 2 and an incident form (in protocol 2 table 2c) will be completed and attached to Datix. For cyber incidents table 2d will be used to assess the threshold for reporting an incident. For data quality issues table 2e will be used to assess the threshold for reporting an incident.

1.11 If any member of staff is unsure about reporting an incident – for example, raising

concerns about a colleague's practice – or wishes to report an incident in confidence, they are advised to contact the Freedom to Speak up Guardian who will assist them in the process. From 1st April 2017, reports of concern can also be raised via a designated raising concerns link captured on Datix. Further guidance can also be found in Raising Concerns at Work – Whistle Blowing Policy (HR 16).

1.12 Patient safety incidents can also be reported directly to the NRLS using their e-reporting facility. This is anonymous, and unless the reporter specifically instructs the NRLS to inform the Trust that the report has been made the Trust is not told. For this reason staff are encouraged to use the internal reporting systems of the Trust in the first instance or following any report to NRLS so that organisational learning can occur. However staff can access this facility via the Intranet front page NRLS link, or by visiting http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/

1.13 Guidance on informing patients when they have been the victim of an adverse event can be found in the Being Open Policy (OP60). A formal being open process is directed where moderate, severe (major) harm or above has been caused. Staff are reminded of their duty to disclose under the Duty of Candour introduced by the Francis Report Feb 2013. Documented records of communications, meetings etc. with the patient and or relatives are required and templates are provided in the Being Open Policy (OP60). Staff must also liaise with Legal Services in instances where the Trust insurers (NHS Resolution) must be informed. Please refer to section 3.6 below of this procedure.

1.14 The Trust seeks to promote a fair, honest and open ('just') culture and encourages staff to look at systems and processes; and to look critically at their own action and those of their teams because it recognises that quality of care can be enhanced by reducing the recurrence of incidents and near misses.

Therefore the Trust will not consider disciplinary action except in the following instances:

- Acts of gross misconduct / criminal acts;
- Professional malpractice;
- Abuse of clients / patients;
- Repeated occurrences involving the same individual;
- Failure to report an incident in which a member of staff was involved or about which they were aware.

In determining courses of action such as suspension, temporary relocation, modification of duties etc managers are directed (where appropriate) to use the NPSA Incident Decision Tree (IDT). The IDT has been developed to help NHS managers and senior clinicians to determine a fair and consistent course of action to take with staff following a patient safety incident.

Guidance on how the IDT works is available at:

http://www.suspension-nhs.org/Resources/Safety%20-%20IDT%20(info%20and%20advice%20on%20use).pdf

1.15 Incidents /near misses relating to equipment must be dealt with as follows:

- Medical device incidents/near misses – refer to HS11 Management of Medical

Devices

- All other equipment incidents/near misses –
  1. Take out of service immediately;
  2. Put a note on the equipment to identify it is out of service;
  3. Report incident on Datix;
  4. Inform manager of the area in which the incident/near miss occurred;
  5. Report to the relevant department for repair/replacement :
     - IT equipment – IT department 8888;
     - Other equipment – Estates Helpline 8999;
     - Anything not covered by Trust – the supplier;
  6. If equipment is not repairable – a condemnation certificate must be provided (refer to HS11 process).

Equipment must not be reinstated unless it is repaired and fully operational, always check equipment for safety prior to use.

Further advice can be sought from your Health and Safety Officer.

1.16 All incidents in the NHS National Screening Programmes e.g. NHS Cancer Screening programmes must be managed in line with the 'Managing safety incidents in NHS Screening Programmes' guidance at Managing safety incidents in NHS Screening Programmes (publishing.service.gov.uk).

2.0 Incident Investigation Management

2.1 The Categorisation Matrix (Attachment 1) gives guidance to all staff as to how and when incidents must be reported and managed dependent on the severity grading. Further guidance on investigation can also be found in Protocol 2: Reporting and Investigation of Serious incidents.

2.2 For any reported incident whereby a member of staff sustains an injury at work that means they are unable to fulfil their duties or a member of the public receives hospital treatment for an accident caused by the estate please see Protocol: 1 RIDDOR.

2.3 Evidence of investigation of incidents or action taken must be attached to the Datix record. This enables high-level scrutiny of the database to enhance organisational learning, and also provides a clear audit trail of the investigation process.

2.4 All employees, regardless of position or profession, have a duty to comply with the investigation of adverse events (incidents, complaints and claims) as indicated in their terms and conditions of employment. Failure to do so may result in disciplinary action.

2.5 The Trust Governance and Risk Management Framework provides clear pathways through the organisation for reporting and review of incidents through Trust and local governance meetings.

2.6 Any action plans developed as a result of incident investigation must be monitored and followed up by the appropriate local governance meeting to provide assurance of local redress. SUI action closure must then be centrally updated within Datix. In addition the tracking of actions resulting from serious/reportable incidents is monitored by a designated Trust level group.

2.7 Staff with responsibility for investigating serious or reportable incidents – (see Protocol 2: Reporting and Investigation of Serious Incident) will undergo training and/or be given guidance/supervision in the practice and principles of root cause analysis (RCA) investigation. RCA investigation training is provided for any staff undertaking RCA investigations and can be booked by contacting the Governance Department. Face to face and virtual training is available via Microsoft Teams. Refer to 8.2.2 of the main policy for details of the frequency and booking of RCA training.

A register will be held centrally of staff who completed RCA training and who may therefore lead/supervise the investigation of more serious/complex incidents. Further guidance on the management and reporting of serious incidents can be found in Protocol 2: Reporting and Investigation of Serious incidents.

On determination that an investigation is necessary, a Divisional Lead and RCA Lead Investigator will be appointed. The RCA Lead Investigator will be responsible for co-ordinating all persons, documentation and preparing a final report.

RCA investigations resulting from serious and reportable incidents will be reviewed and agreed at Directorate and Divisional level followed by Executive sign off at the Executive Significant Event Review Group (ESERG). A serious incident report is presented at the Quality and Safety Advisory Group (QSAG). A RCA Table Top meeting has been established and all STEIS reportable incidents will be subject to a RCA Table Top meeting (excluding serious falls, healthcare acquired pressure ulcers, infection outbreak and maternity incidents which undergo separate and specific scrutiny group review).

2.8 A generic RCA Template is provided in (Attachment 2a and Attachment 2b) for incident investigation. There are specialist templates for the following:

- Infection prevention;
- Slips/Trips/Falls;
- Pressure Ulcers;
- VTE.

Further guidance can be found in the related policies (refer Protocol 2 for related policy requirements). Guidance for Complaint investigation is provided within Complaints Policy (OP 08), Procedure 2 and for Claims within the Claims Policy (OP 31) Attachment 1.

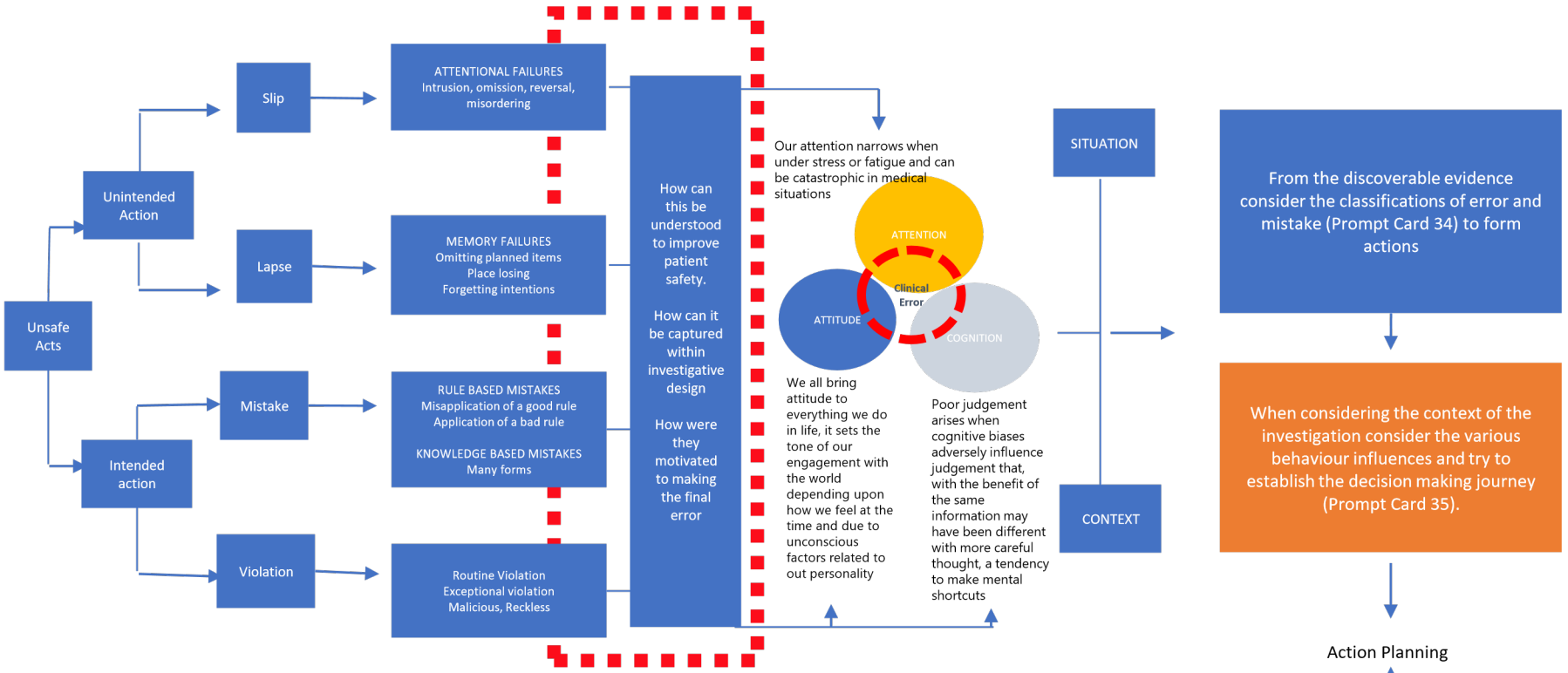
To support the identification of human factors (including error or behaviors) and to enable learning and improvement where these features present as root or contributory causes, the RCA investigation has been enhanced to enquire further into the type and level of error and any behavioral influences. This will enable the identification of appropriate redress actions for the event and consideration of wider system/process adjustments that could be made. Attachment 2c illustrates a human error classification for reference and related prompts are guided in the RCA template in attachment 2b.

Reason-Human Error-Error Classification

Kahneman & Tversky clinical error at the centre of medical incidents, affected by heuristics and cognition

Russell Kelsey –Investigating & Reporting Serious Clinical Incidents – a useful construct poses clinical error is at the centre of three influences of which motivate behaviour

Systems Theory (Behaviour)



Identified from the situation and discoverable evidence

Identified from the context – on a balance of probabilities

2.9 Learning from an adverse event is defined as taking safety-related steps to impact policy, practice and/or process issues that have contributed to the incident. Lessons and good practice from which others can learn will be shared as follows within the organisation.

Local

- With patient and their family / carers directly involved with the incident where appropriate (in line with Being Open OP 60) – via meetings and letter communication.
- Staff / areas directly involved with the incident – via de-brief sessions, one to one meeting between staff and managers and, team/governance meetings as appropriate.
- Similar services / specialities– via communication across divisional governance groups, newsletter communications and where appropriate review of related policies and processes.
- Review of incidents (including serious incidents) and actions taken at monthly Directorate / Department governance meetings (including sign off of RCA / action plans)

Organisational

- Review of investigation outcomes for all serious incidents at the Trust level group to establish system / process / policy changes necessary.
- Review findings and lessons from incidents ,claims, complaints and inquests and monitor trust-wide learning through qualitative and quantitative trend analysis to extract common themes and necessary actions (local and trust wide) via the Learning from Experience (LEG).
- Review of relevant staff training programmes at Trust and local levels to incorporate lessons.
- Apply two-way organisational learning from regional networks/ patient safety forums, NPSA incident summary reports and benchmarks, conferences, workshops and seminars.
- Implement a Learning Framework with a core focus on anaylsing data, identifying and implementing learning, building experiential learning capability and measuring change/improvement resulting from the embedding of lessons learned.
- The Trust uses multiple forms to publish learning including Making it Better Alerts (MIBA), Risky Business publications, Shared Learning reports and RCA spotlight reports.

2.10 Where incidents, claims or complaints have crossed organisational boundaries (e.g. involved RWT and other agencies such as Social Services or an independent provider), the appointed RWT investigator will be responsible for liaising with the relevant leads in the other organisations involved.

2.11 The Governance Department, Division and Directorates are responsible for ensuring that any lessons learned from incidents, complaints, claims are disseminated to local and organisational forums (refer 2.9) as appropriate.

2.12 Where investigations or other findings have led to Trust-wide recommended changes

in practice, trend analysis reports will be used to measure compliance with and effectiveness of the changes.

3.0 **Reporting to External Specialist Agencies – incidents are reported as above using the trust reporting system.** Leads are identified for reporting to external agencies from the appropriate department/service relevant to the external agency remit. Where reports do not originate from the source department leads are notified by local reporters and/or the leads have access to the Datix system to review reports of relevant incidents. All reports made by leads to external agencies must be updated on Datix and report document uploaded where appropriate. The following paragraphs (3.1 to 3.15) identify externally reportable incidents to specialist agencies and the means of reporting **(where any of the following also meets the criteria for a serious/reportable incident the process in Protocol 2 also applies)**:

3.1 **National Reporting Learning System** – All patient safety incidents will be reported electronically via DATIX to the National Reporting Learning System by the Governance and Legal Services Department. **Serious incidents (as indicated in Protocol 2) must be entered into the NRLS (via STEIS) within 2 working days**. This contributes to the national learning about patient safety. Reports will be received from the NRLS and distributed through the organisation, which can be used to benchmark incident reporting with other organisations and identify areas for improvement.

3.2 **Health and Safety Executive (HSE)** – The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995 (amended 2013) informs the Trust that it must report deaths, major injuries, and accidents resulting in over 7 day injury, diagnosed diseases, dangerous occurrences and gas incidents (refer Protocol 1). The Health and Safety Team will carry out RIDDOR reporting to the HSE. Forms must be completed by Department Managers and returned to the H&S Team, Governance Department.

3.3 **Medicines and Healthcare Products Regulatory Agency (MHRA)** – Where an adverse incident involved a medical device / pharmaceutical/consumable the

Trust's nominated liaison officer with the MHRA (within Medical Physics, Pharmacy, Procurement or Estates) must be contacted within 24 hours. Refer: Management of Medical Devices (HS11)

3.4 **Clinical Commissioning Group (CCG)** – All incidents that match the National SUI framework guidance for serious and reportable incidents will be reported both internally and to the CCG by the relevant Healthcare Governance Manager. **Such incidents must be reported to the STEIS reporting system by 17:00 within 2 working days of the event or knowledge of the event**. In office hours, for serious incidents meeting the criteria (see Protocol 2: Reporting and Investigation of Serious Incidents) the Trust may contact the CCG Risk Management Team for guidance and support and to agree whether the situation requires escalation and if so will agree any action that needs to be taken with the Trust.

3.5 **Coroner's Office** – Medical staff are obliged to notify the coroner of any deaths which meet the criteria below (Refer also to the Death Certification and Learning from Deaths Policy OP87):

Obligations when reporting the following to Her Majesty's Coroner:

- All deaths which occur within 24 hours of hospital admission (except for natural causes where the Medical Examiner has reviewed the Medical certificate of cause of death (MCCD)). This rule applied to the 0-18 age range also except for sudden unexpected death in infancy (SUDI) which must continue to be reported to the Coroner.
- All neonatal deaths are referred to the Medical Examiner (ME) and if a natural cause of death is agreed these deaths are not referred to HM Coroner. (Stillbirths are not routinely referred to HM Coroner)
- All SUDIs (Sudden Unexpected Deaths in Infancy) are referred to HM Coroner
- All baby deaths (excluding termination of pregnancy) are referred to CDOP (Child Death Overview Panel).

Revised guidance for registered medical practitioners on the Notification of Deaths Regulations (March 2020) – Circumstances in which a notification should be made under regulation 3 (Procedure 1 Attachment 1):

- The death was due to poisoning including by an otherwise benign substance,
- The death was due to exposure to, or contact with a toxic substance,
- The death was due to the use of a medicinal product, the use of a controlled drug or psychoactive substance,
- The death was due to violence, trauma or injury,
- The death was due to self-harm,
- The death was due to neglect, including self-neglect,
- The death was due a person undergoing any treatment or procedure of a medical or similar nature,
- The death was due to an injury or disease attributable to any employment held by the person during the person's lifetime,
- The person's death was unnatural but does not fall within any of the above circumstances,
- The cause of death is unknown,
- The registered medical practitioner suspects that the person died whilst in custody or otherwise in state detention,
- There was no attending medical, and there is no other registered medical practitioner to sign a medical certificate cause of death in relation to the deceased person,
- Neither the attending medical practitioner, nor any other medical practitioner able to sign the medical certificate cause of death, is available within a reasonable time of the person's death to sign the certificate of cause of death,
- The identity of the deceased person is unknown.

Any queries or doubts concerning the notification or reporting to the HM Coroner are to be referred to the Trust Medical Examiner's Office.

3.6 **NHS Resolution (NHSR)** – Any adverse incident, complaint and/or serious adverse outcomes representing a significant litigation risk will be reported to the NHSR by the Legal Services Manager. Staff must notify the Legal Services Manager(s) who will inform the NHSR where the following features arise:

- Fatal incidents;
- MP involvement;
- Media attention;
- Human rights issues;
- Multi-party actions;
- Multiple claims from a single cause;
- Novel (new, unique, unusual), contentious (sensitive, complex) or repercussive (litigation likely to ensue) claims.

From 1st April 2017 NHSR require Trusts to report incidents that are likely to result in severe brain injury, as defined below:

Babies born at term (≥37 completed weeks of gestation), following labour, with a severe brain injury diagnosed in the first seven days of life, namely babies that have one or more of the following:

- Diagnosed with grade III hypoxic ischaemic encephalopathy (HIE);
- Actively therapeutically cooled;
- Have all three of the following signs: decreased central tone; comatose; seizures of any kind.

Reporting is mandatory within 30 days of the incident (refer protocol 2 for the process of reporting to NHSR).

3.7 **Care Quality Commission (CQC)** – The Trust must notify CQC about events which indicate risks to on-going compliance with the Fundamental Standards of Care. Examples of notifications are listed in Protocol 2: Reporting and Investigation of Serious incidents.

3.8 **Information Commissioner (ICO)** – Reports of serious Information Governance incidents at level 2 or more (* see IG severity table in Protocol 2) involving incidents which will typically breach one of the principles of the Data Protection Act, General Data Protection Regulations and/or the Common Law Duty of Confidentiality. This includes unlawful disclosure or misuse of confidential data, recording or sharing of inaccurate data, information security breaches and inappropriate invasion privacy – refer Protocol 2 below for CCG reporting)

3.9 **NHS Security Management Service (NHSSMS)/NHS Protect** – as of 31st March 2017 NHS Protect ceased to exist for security management as the organisation will focus solely on counter fraud. Therefore the Security Incident Reporting system (SIRS) will cease to operate. All security incident reports must continue to be made via Datix.

3.10 **Local Safeguarding Children / Adult Boards (LSCB and LSAB)** – Require the notification of serious safeguarding concerns / events / incidents and individuals involved. Ref: www.wolverhamptonsafeguarding.org.uk, RWT Safeguarding Children Policy (CP41), RWT Safeguarding Adults at Risk Policy (CP53), RWT Dealing with a

disclosure against staff indicating unsuitability to work with children or adults with needs of care and support (HR10).

3.11 **Health Protection Agency (HPA)** – Required reporting includes outbreaks of infectious diseases, hazardous incidents involving chemicals**,** poisons or radiation. The lead for reporting is based within the Infection Prevention Team.

3.12 **Serious Hazards of Transfusion (SHOT) Scheme** – Serious adverse events and serious adverse reactions relating to blood transfusion must be reported. The lead for reporting is based within the Pathology Department.

3.13 **Ionising Radiation (Medical exposure) Regulations (IRMER)** - Radiation incidents are required to be reported externally where the dose is unintended or much greater than intended. Refer: Procedure for reporting and investigation of radiation incidents involving patients (HS 05). The lead for reporting is based within the Medical Physics and Clinical Engineering Department.

3.14 **Human Tissue Authority** – Reports of untoward occurrence (including reaction) associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity. Refer: Bone Bank Policy and Manual (CP 24). The lead for reporting is based within the Bone Bank Team.

3.15 **Professional regulators and professional misconduct** – If grounds of professional misconduct are suggested within a serious incident it is important that the appropriate lead (e.g. Responsible Officer/Medical or Nurse Director) within the organisation is alerted (within 2 days) to ensure the appropriate action is taken. Appropriate action includes investigation and/or HR team taking time to carefully assess or refer on to experts the actions or omissions in question in the context of the incident, to identify whether these are considered reckless or malicious, as opposed to slips, lapses, or situations where others are taking the same route and in need of support, supervision or training.

N.B This list is not exhaustive.

In addition to information provided above the NPSA have developed a useful resource to support the reporting to external agencies [http://www.npsa.nhs.uk/nrls/reporting/patient-safety-direct/]

Ministry of Justice

Revised guidance for registered medical practitioners on the Notification of Deaths Regulations

March 2020

The Notification of Deaths Regulations 2019 are modified when specific provisions in the Coronavirus Act 2020 are implemented.

This revised Guidance applies only when the modified Regulations are in force.

No other version of this Guidance should be used during that period.

This revised Guidance will no longer apply once the modified Regulations cease to be in force.

If you are unsure whether this revised Guidance applies, please contact coroners@justice.gov.uk.

The revised guidance is highlighted in the pink text boxes.

Contents

The notification requirement

The Notification of Deaths Regulations 2019 are modified when specific provisions in the Coronavirus Act 2020 are implemented.

This revised Guidance applies only when the modified Regulations are in force.

No other version of this Guidance should be used during that period.

This revised Guidance will no longer apply once the modified Regulations cease to be in force.

When the modified Regulations are in force there is no duty to notify a death to the coroner where there is a medical practitioner who may complete the medical certificate cause of death (MCCD) within a reasonable time period. Guidance on who may complete the MCCD when the modified Regulations are in force is available here. https://www.gov.uk/government/publications/guidance-notes-for-completing-a-medical-certificate-of-cause-of-death

Therefore, the duty to notify only applies where there is no medical practitioner who may complete the MCCD.

1. A registered medical practitioner means a person on the General Medical Council's list of Registered Medical Practitioners, who has a licence to practise.

2. It is anticipated that in practice, where available, it will be the medical practitioners who is qualified to complete the medical certificate cause of death (MCCD) who will be making the notification to the senior coroner.

3. A death may have already been reported to the coroner by a person other than a medical practitioner, such as a friend or family member of the deceased, or the police. Such reports will not usually include the information required at regulation 4(3) and (4), and may not provide the coroner with the full medical picture.

4. Therefore, even if a medical practitioner is aware that someone other than a medical practitioner has reported a death to the coroner, the registered medical practitioner should still make a notification under the Regulations.

Whilst Covid-19 is a notifiable disease under the Health Protection (Notification) Regulations 2010, a death caused by Covid-19 virus is not reason of its own to notify the death to the coroner.

Covid-19 is an acceptable direct or underlying cause of death

Circumstances in which a notification should be made under regulation 3

5. A death under the circumstances set out as follows should always be notified, regardless of how much time has passed since the death.

6. A death must be notified to the relevant senior coroner where there is reasonable cause to suspect that the death was due to (that is, more than minimally, negligibly or trivially) caused or contributed to by the following circumstances:

The death was due to poisoning including by an otherwise benign substance

7. This applies to deaths due to the deliberate or accidental intake of poison, including any substance that would otherwise be benign, beneficial or tolerable but at certain levels is injurious to health, such as sodium (salt).

8. In regard to alcohol or smoking related deaths, only those due to acute poisoning should be notified to the coroner. Deaths due to natural chronic/long lasting conditions (caused by alcohol or cigarette consumption) should not be notified to the coroner.

The death was due to exposure to, or contact with a toxic substance

9. This applies to any cases where death was due to the exposure to a toxic substance. Examples of this include, but are not limited to deaths due to:

    1) Toxic material, including toxic solids, liquids and gases.

    2) Radioactive material.

The death was due to the use of a medicinal product, the use of a controlled drug or psychoactive substance

10. This applies to deaths due to either the deliberate or accidental intake or administration of medicinal products or any other drugs, or any complications arising from this. Examples of this include, but are not limited to:
    1) Illicit, or recreational drugs.
    2) Medical drugs, including but not limited to, prescribed or non-prescribed medication (e.g. a self-administered overdose or an excessive dose given either in error or deliberately).

11. Any circumstance where the death may be due to a psychoactive substance should be notified to the coroner. A psychoactive substance includes any substance which is capable of producing a psychoactive effect in a person if, by stimulating or depressing the person's central nervous system, it affects the person's mental functioning or emotional state. Examples of this include, but are not limited to:
    1) New psychoactive substances, also known as 'legal highs' or 'designer drugs'.
    2) Herbal highs, such as salvia.

The death was due to violence, trauma or injury

12. A death may be considered due to violence, trauma or physical injury where, for example, the deceased:
    1) Died as the result of violence, trauma or injuries inflicted by someone else or by themselves.
    2) Died as the result of violence, trauma or injuries sustained in an accident, such as a fall or a road traffic collision.

The death was due to self-harm

13. This may apply if it is reasonable to suspect that the deceased died as the result of poisoning, trauma or injuries inflicted by his/herself or his/her actions.

The death was due to neglect, including self-neglect

14. Neglect applies if the deceased was in a dependent position (e.g. a minor, an elderly person, a person with a disability or serious illness) and it is reasonable to suspect that there was a failure to provide them with – or to procure for them – certain basic and obvious requirements. This would include, for example, a failure, omission or delay by any person to provide or procure:
    1) Adequate nourishment or liquid.
    2) Adequate shelter or warmth.
    3) Adequate medical assessment, care, or treatment.

15. This also includes a death, albeit from natural causes, where it is reasonable to suspect that the death results from some human failure, including any acts/omissions.

16. Self-neglect applies if the death is a result of the deceased intentionally or unintentionally not preserving their own life. However, this does not include circumstances where there has been a documented, reasonable and informed decision by the deceased not to act in a way that would have preserved their own life. This may include a decision not to take a certain course of treatment.

17. There may be cases where people fail to take adequate nourishment or proper personal care due to the natural progression of an underlying illness, such as dementia. Although this may hasten their death, this death should not be notified to the coroner unless there was neglect by others.

18. It does not extend to deaths where the lifestyle choices of the deceased – for example, to smoke, eat excessively, or to have a chronic alcohol condition – may have resulted in their death.

The death was due to a person undergoing any treatment or procedure of a medical or similar nature

19. This applies if the death may be related to surgical, diagnostic or therapeutic procedures and investigations, anaesthetics, nursing or any other kind of medical care. It includes scenarios such as:
    1) Death that occurs unexpectedly given the clinical condition of the deceased prior to receiving medical care.
    2) Errors made in the medical procedure or treatment e.g. the deceased was given an incorrect dosage of a drug.

3) The medical procedure or treatment may have either caused or contributed to death (as opposed to the injury/disease for which the deceased was being treated).
4) Death follows from a recognised complication of a procedure that has been given for an existing disease or condition.
5) The original diagnosis of a disease or condition was delayed or erroneous, leading to either the death or the acceleration of the death.

20. It should be noted that a death that has occurred following a medical or similar procedure may not necessarily be due to that treatment; the medical practitioner should consider whether there is a relationship. It is only in circumstances where the medical practitioner believes that the death was due to this procedure that the death should be notified.

The death was due to an injury or disease attributable to any employment held by the person during the person's lifetime

21. This includes injuries sustained in the course of employment (including self-employment, unpaid work, work experience or contracted services), for example if the death was due to a fall from scaffolding, or being crushed in machinery. It also includes deaths that may be due to diseases received in the course of employment even if the employment has long ceased.

22. Diseases in the course of employment made include, for example:
    a. A current or former coal miner who died of pneumoconiosis.
    b. A current or former furniture worker who died of cancer of the nasal sinuses.
    c. A current or former construction worker who died of asbestos-related lung- disease e.g. asbestosis or mesothelioma.
    d. A current or former rubber or paint worker who died of bladder cancer.

The person's death was unnatural but does not fall within any of the above circumstances

23. A death is typically considered to be unnatural if it has not resulted entirely from a naturally occurring disease process running its natural course, where nothing else is implicated. For example, this category includes scenarios in which the deceased may

have contracted a disease (e.g., mesothelioma) as a result of washing his/her partner's overalls which were covered in asbestos however long before the death occurred.

The cause of death is unknown

24. The duty to notify the coroner of unknown causes of death applies to an attending medical practitioner who is unable to determine the cause of death to the best of their knowledge and belief, based upon a conscientious appraisal of the known facts, including after suitable consultation with colleagues or a medical examiner.

The registered medical practitioner suspects that the person died while in custody or otherwise in state detention

25. This is relevant where the person was compulsorily detained by a public authority regardless of the cause of the death. This applies whether the custody or state detention was in England and Wales or elsewhere and includes:
    1) Hospitals, where the deceased was detained under mental health legislation (including instances when the deceased is on a period of formal leave).
    2) Prisons (including privately run prisons).
    3) Young Offender Institutions.
    4) Secure accommodation for young offenders.
    5) Secure accommodation under section 25 of the Children Act 1989.
    6) Any form of police custody e.g. the deceased was under arrest (anywhere) or detained in police cells.
    7) Immigration detention centres.
    8) Court cells.
    9) Cells at a tribunal hearing centre.
    10) Military detention.
    11) Bail hostel.
    12) When the deceased was a detainee who was being transported between two institutions.
    13) Any death in which the person would ordinarily have been in state detention but had been temporarily released (for example for medical treatment) or had absconded from detention.

26. This does not include circumstances where the death occurred while the deceased was subject to a Deprivation of Liberty Order unless the person was additionally subject to custody or detention as described at paragraph 25 above.

There was no attending registered medical practitioner, and there is no other registered medical practitioner to sign a medical certificate cause of death in relation to the deceased person

When the modified Regulations are in force, the death must be notified to the coroner if there is no attending medical practitioner who is required to sign the MCCD **and** there is no other medical practitioner who may sign the certificate within a reasonable time period.

The notifying medical practitioner will need to provide the coroner with relevant medical and supporting information.

Neither the attending medical practitioner, nor any other medical practitioner able to sign the medical certificate cause of death, is available within a reasonable time of the person's death to sign the certificate of cause of death

When the modified Regulations are in force if there is a medical practitioner who is able to sign the MCCD (either as the attending medical practitioner, or otherwise), but no such person is able to sign the certificate within a reasonable time period, then the death must be notified to the coroner.

It is ultimately for the discretion of a medical practitioner to determine what would be a 'reasonable time' based on the individual circumstances of the case. It is recommended that where there is a doctor able to complete the MCCD, they should be completing an MCCD as soon as possible.

It should be noted that a death must legally be registered within 5 days from the date of death, and the MCCD is needed for this registration to be made within this time limit. Therefore, completion of the MCCD should not exceed this time limit.

The identity of the deceased person is unknown

27. If the identity of the deceased is not known, then it follows that there will be no attending medical practitioner and/or the deceased's medical history is unknown, precluding the completion of an MCCD. In this scenario the death must be notified to the senior coroner.

28. Where the identity of the deceased is unknown it is recommended that the death is also reported to the police.

Information to be provided to the senior coroner

Information to be provided to the senior coroner

29. Regulation 4(1) requires the notification to the senior coroner to be made as soon as is reasonably practicable after the medical practitioner has determined that the death should be notified. While the regulations do not prescribe a specific time limit for notifications this notification should be prioritised. If the death arises from an event or occurrence that may be suspicious then the police should be informed immediately.

30. The medical practitioner should usually take reasonable steps to establish the cause of death before notifying the coroner. This may include seeking advice from another medical practitioner, such as a medical examiner or any other responsible consultant. However, where the death is clearly unnatural it may be more appropriate for a notification to be made to the senior coroner straight away.

Written Notifications

31. Notifications in writing include submission of documents by courier or electronically (including email, web portal or other scanning methods).

Oral Notifications

32. Regulation 4(2) allows a notification to be provided orally in exceptional circumstances. It is expected that medical practitioners will operate with IT systems which will facilitate the electronic transfer of information and records to the coroner, which includes the scanning of paper records and documents or the creation and transfer of electronically stored records and documents.

33. However, there may be circumstances or occasions where the IT infrastructure or systems required to facilitate the transfer of information, records and documents is not available in order for a timely written notification to be made to the coroner. Where the notifying medical practitioner does not have access to the facilities required to make a notification in written form you should inform the coroner of the reasons for this when making an oral notification.

34. Oral notifications may include notification by telephone.

35. Following an oral notification, the notifying medical practitioner must, as soon as is reasonably practicable provide a written notification, confirming the information given in the oral notification.

The Notification

36. Regulation 4(3) and 4(4) prescribes the information that a medical practitioner must, in so far as it is known to them, provide to a senior coroner when making a notification. If this information is not known to the medical practitioner, they do not have a duty to provide it as part of their notification.

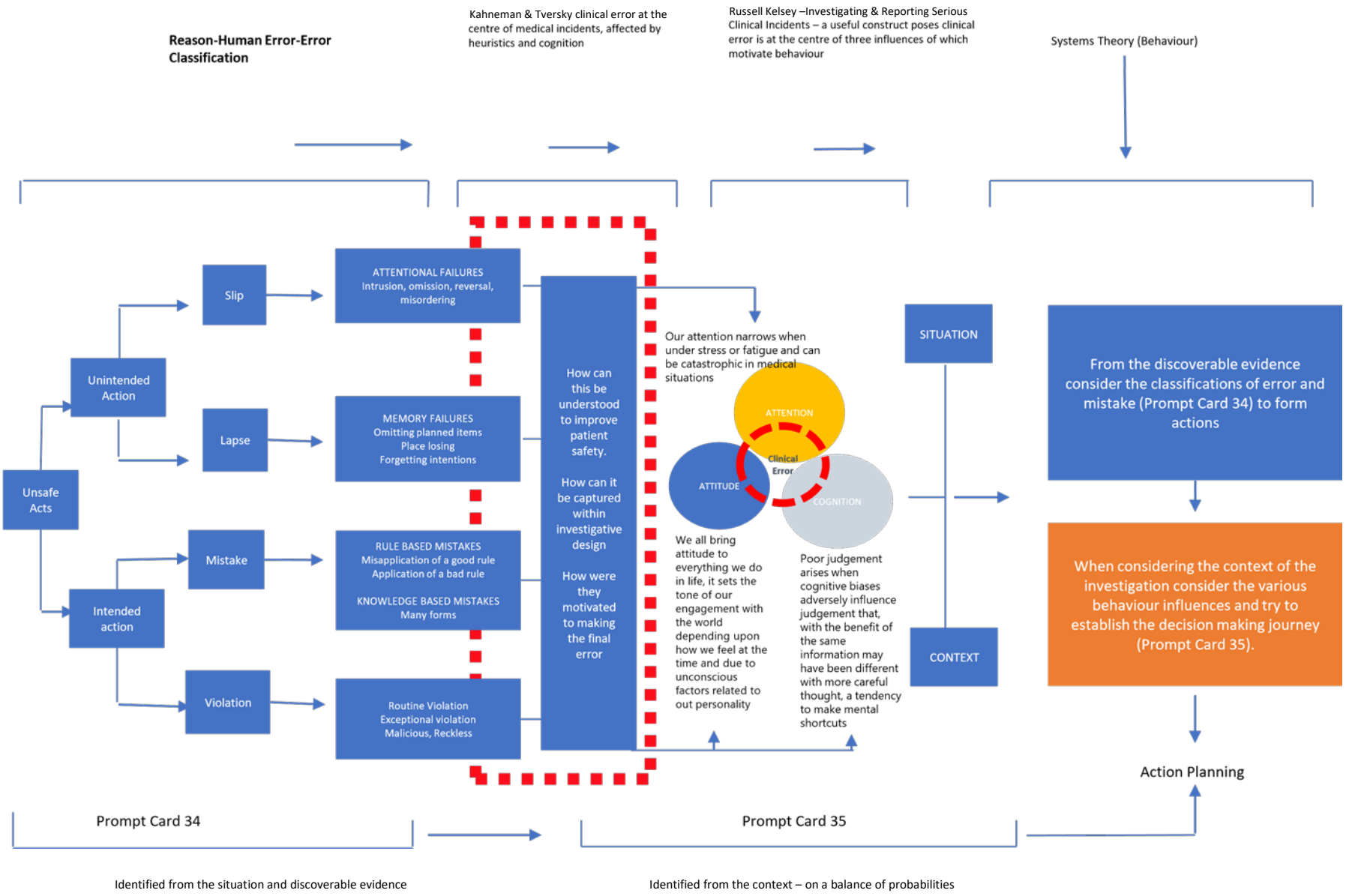
37. Regulation 4(3)(c) requires the medical practitioner to provide to the coroner the name of the next of kin or, where there is none, the person responsible for the body of deceased. Where there is no identifiable person who may be responsible for the body, the medical practitioner should provide the name of the Local Authority who will be responsible for the disposal of the body.

38. Regulation 4(3)(d) requires that the medical practitioner indicate the reason why it is deemed that the death should be notified. The Regulations do not specify how this notification should be made and in certain circumstances it may be sufficient to refer simply to the sub-paragraph number within Regulation 3(1). However, it is expected that in most cases, the notifying medical practitioner will provide a detailed explanation of the likely cause of death in narrative form. Where possible, this should include the proposed medical cause of death and an explanation of any technical terms used.

39. Regulation 4(4) requires the medical practitioner to provide any further information that they consider to be relevant to the coroner. It is recommended that the medical practitioner making the notification provides their GMC number in this section. This provision allows for circumstances where a coroner requests medical practitioners to include information relevant to their investigation that is additional to that specifically listed within the Regulations.

40. A coroner's investigation may not be necessary in all notifiable cases. If the senior coroner is satisfied that he/she does not need to open an investigation then he/she may issue a 100A form, or refer the case back to the medical practitioner, who can issue a medical certificate of cause of death. For example, this might happen if the deceased was receiving palliative care at home, and this was documented in the general practitioner notes, but the general practitioner was unavailable at the time of notification. If this occurs, a clear record should be made in the patient notes by the medical practitioner who notified the death to the coroner, detailing the notification and subsequent re-referral back to the medical practitioner by the coroner.

Alternative format versions of this report are available on request from coroners@justice.gov.uk


Reason-Human Error-Error Classification
Kahneman & Tversky clinical error at the centre of medical incidents, affected by heuristics and cognition
Russell Kelsey –Investigating & Reporting Serious Clinical Incidents – a useful construct poses clinical error is at the centre of three influences of which motivate behaviour
Systems Theory (Behaviour)
Unsafe Acts
Unintended Action
Intended action
Slip
Lapse
Mistake
Violation
ATTENTIONAL FAILURES
Intrusion, omission, reversal, misordering
MEMORY FAILURES
Omitting planned items
Place losing
Forgetting intentions
RULE BASED MISTAKES
Misapplication of a good rule
Application of a bad rule
KNOWLEDGE BASED MISTAKES
Many forms
Routine Violation
Exceptional violation
Malicious, Reckless
How can this be understood to improve patient safety.
How can it be captured within investigative design
How were they motivated to making the final error
Our attention narrows when under stress or fatigue and can be catastrophic in medical situations
ATTENTION
ATTITUDE
COGNITION
Clinical Error
We all bring attitude to everything we do in life, it sets the tone of our engagement with the world depending upon how we feel at the time and due to unconscious factors related to out personality
Poor judgement arises when cognitive biases adversely influence judgement that, with the benefit of the same information may have been different with more careful thought, a tendency to make mental shortcuts
SITUATION
CONTEXT
From the discoverable evidence consider the classifications of error and mistake (Prompt Card 34) to form actions
When considering the context of the investigation consider the various behaviour influences and try to establish the decision making journey (Prompt Card 35).
Action Planning
Prompt Card 34
Prompt Card 35
Identified from the situation and discoverable evidence
Identified from the context – on a balance of probabilities

1.0 Risk Assessment and Registers

1.1 The Trust has identified three levels of risk register: Local (Directorate), Division and Trust (i.e. Trust Risk Register and the Board Assurance Framework)

1.2 Actual and potential risks are identified from numerous sources including incidents, complaints, claims, trends, investigations, compliance, benchmark audits, inspections / assessment. Staff are instructed via training and the requirements of this Policy to identify, manage and escalate risks from all sources of service activity.

1.3 Risks are identified at three levels.

Local Directorate

- Directorate operational risks which affect the everyday business of the area / department and can usually be managed within the local department /directorate.

Local Divisional

- Operational risks which may have been identified in more than one area or which cannot be managed within a Department / Directorate and which therefore need to be managed and monitored at Divisional level rather than in one discreet area. For monitoring and oversight the Divisional risk register also includes all risks escalated from Directorates to the Trust Risk Register.

***** Refer to the Trust categorisation matrix for frequency of local risk and risk register review.

Trust:

Trust Risk Registers:

- The Trust Risk Register contains high level operational or strategic risks escalated from Directorate and Divisional risk registers. It forms an audit trail of the process for risk identification, prioritisation, treatment and escalation from operational service areas to the Board of Directors. It informs the Assurance Framework and provides the link between local risk management processes and board level review of operational/strategic risk. The Trust Risk Register will automatically include all approved risks graded as 12 or above using the Categorisation Matrix (Attachment 1). The Trust Risk Register is reviewed by the designated Trust level Committee and regularly reported to the Trust Board.

Board Assurance Framework (BAF):

- The Board Assurance Framework details the principal risks to meeting Trust strategic objectives. The BAF links risk, controls and assurances to the Trust objectives and provides a structure to support internal controls and the Annual Governance Statement. Strategic risks are owned and managed by Executive Directors and reported to the Trust Board through a Trust Risk Register and Board Assurance Framework.
- The Board Assurance Framework details the strategic risks linked to Trust objectives. The Trust Risk Register and the Board Assurance Framework are regularly monitored by the Trust Assurance Committees and Trust Board.

1.4 The risk register contains the following minimum information:

- Source of risk;
- Description of risk;

- Risk score;
- Controls and gaps in controls;
- Residual risk score;
- Mitigating actions;
- Date of assessment and date for review.

1.5 The escalation of risks through the organisation is described in 3.7 below (reference also the Governance and Risk Management Framework. For an illustration of Directorate/ Divisional/Trust risks flows and escalation see: Procedure 2 Flowchart.

2.0 Risk Assessments

2.1 Guidance on the principles of risk assessment can be found in the Health and Safety Management Policy (HS 01). Although designated as Health and Safety, the information contained within HS01 is equally applicable to risk assessments of any description – clinical, non-clinical, organisational, financial etc. The risk assessment process is consistent throughout the Trust and the same methodology and escalation process is adopted for both clinical and non-clinical risks.

2.2 All areas will have staff who are trained in the principles and practice of risk assessment. Training on Risk Assessment is available from the Health and Safety Team; based in the Governance Department (an annual training plan is available).

2.3 It is the responsibility of area and department managers to ensure that risk assessments are conducted, recorded and monitored by local governance meetings, and that risks which cannot be managed at local level are appropriately escalated as defined in 3.7 below (reference also the Governance and Risk Management Framework).

When new activities or changes to existing activities are contemplated, a risk assessment must be carried out and risks prioritised for entry onto the risk register where an unacceptable level of risk remains after controls and/or on-going monitoring is required.

2.4 It is the responsibility of all employees to work safely in accordance with actions specified in risk assessments. All employees must familiarise themselves with risk assessments specific to their area of work, and must bring to their manager's attention any risks for which there does not appear to be an adequate treatment plan.

2.5 Paper copies of risk assessments must be recorded using the Trust Risk Assessment Form (Attachment 3). Fire Risk assessments must be undertaken by Fire Safety Manager, Senior Fire Safety Advisor or other competent person.

3.0 Risk Registers

3.1 The Risk Register is a discreet module within the Datix system where risks can be entered, updated, monitored and closed. Access to this section of Datix is given to specific trained individuals who are either responsible for entering and retrieving data, or need to interrogate the data for governance purposes. A guided template is created to gather risks information need for entry onto Datix.

Managers and others who carry these responsibilities can apply for training and access by contacting the Governance Department.

3.2 All Directorates have their own section (Local Risk Register) within the Datix system, and must use the register as the basis for discussion and monitoring of their open risks at governance meetings at least quarterly. Decisions concerning

review/management of risks, action plans, re-grading or closing of risks must be evidenced by the minutes of appropriate meetings to provide an audit trail. Where applicable, documents can be attached to the Datix record e.g. action plan, minutes of decisions etc. Risk Leads must ensure that all risks have mitigating controls and action plans in place.

3.3 Under Health and Safety Law the Trust has an obligation to undertake suitable and sufficient risk assessments related to the health and safety of all its employees. These risk assessments must be available and accessible for all staff in either electronic or hard copy format (Refer HS01).

3.4 There is no requirement for these statutory risk assessments to be entered onto the Directorate (Datix) risk registers, unless Departments feel that after implementing all identified control measures an unacceptable level of risk remains. In this instance the risk assessment will be added to the risk register and monitored as described above in 3.2. Risk assessments that are not added to the risk register must be made available to staff and must be reviewed in accordance to the needs of the assessment but at least annually.

3.5 Existing controls must be reviewed to ensure they remain effective, discontinued if no longer required, or where not effective an action plan must be developed to implement new action or enhanced controls to manage the risk.

3.6 As part of regular risk register review, all risks scored below 12 but with a consequence of catastrophic (5) will be specifically assessed for the effectiveness of controls and any change to the risk likelihood. The appropriate Governance Officer will be required to bring these specific risks to the attention of the Directorate Management Team and also the Healthcare Governance Manager in order to seek clarification that the scoring is correct. In the event of the need to further escalate this will follow the agreed principles set out in OP10.

3.7 Risk escalation from local areas is determined by the severity/grade assigned using the Categorisation Matrix (Attachment 1). All risks graded 12 and above must be escalated to appropriate line management for grade approval. Where agreed, the risk must be escalated to Division and subsequently to the Director level for acceptance onto the Trust risk register (refer Operational and Divisional risk flowchart below). Staff must seek advice from management or governance staff if they are uncertain of the grade or rationale for escalation. Any risks graded less than 12 that cannot be controlled at local level must be escalated through the next level of management (e.g. ward to Directorate, Directorate to Division) for consideration.

3.8 A Risk Register Review meeting will oversee the management of operational risks within the Trust Risk Register as well as monitor the appropriate escalation of risks that meet the threshold for escalation.

3.9 Risks to be transferred to the Board Assurance framework are identified/agreed by Director leads.

3.10 It is the responsibility of the Director Lead of a strategic risk to advise the Trust Board on the acceptability or otherwise of the risk faced by the organisation. Where a risk cannot be reduced or eliminated to an acceptable level, the decision to accept the risk must be clearly recorded and auditable via the minutes of the Trust Assurance Committee/Trust Board.

4.0 Risk Tolerance

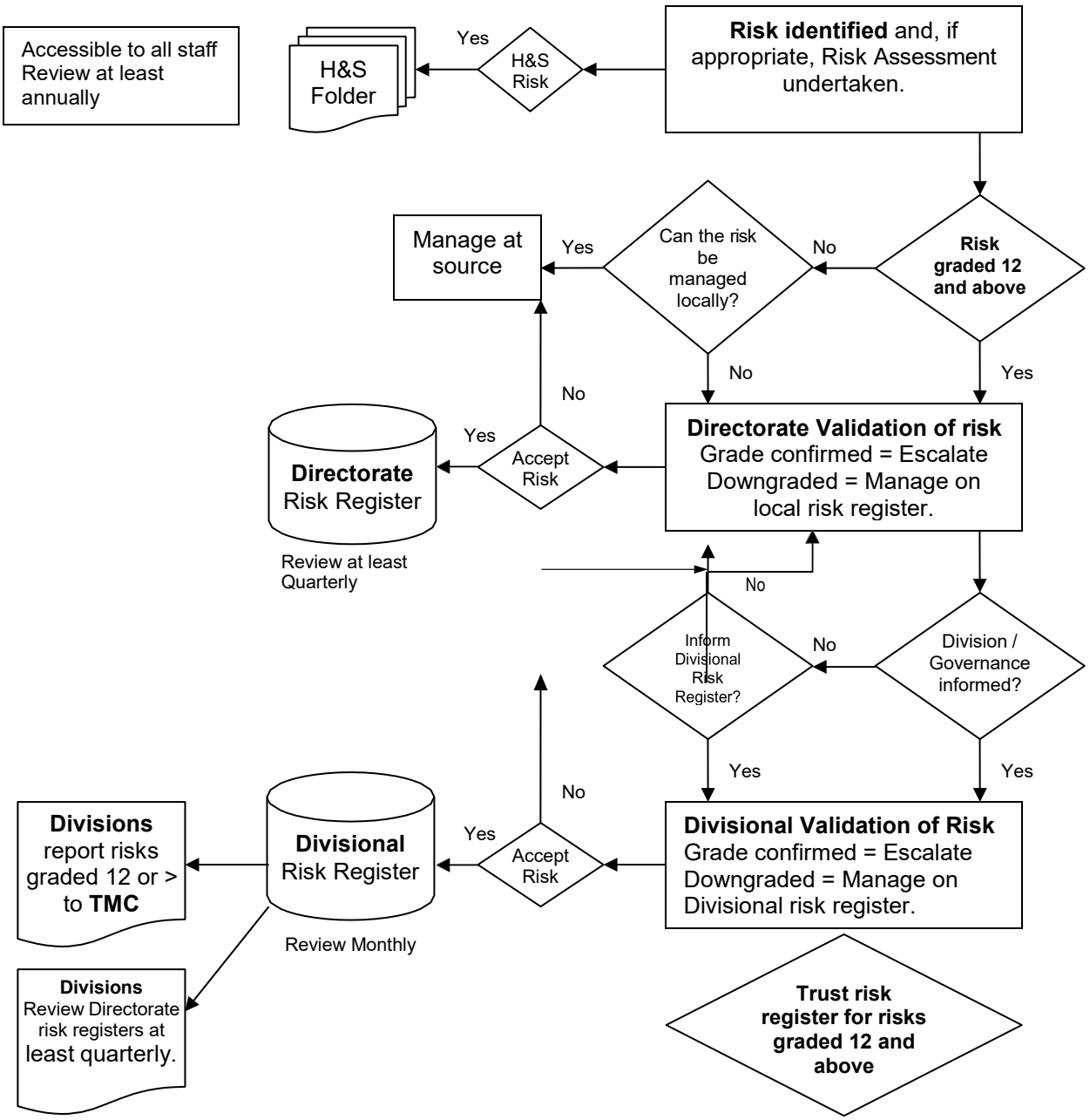
4.1 The level of acceptable risk tolerance will be guided by the Trust Categorisation Matrix (Attachment 1), risk escalation process and ultimately determined by the Trust Board of Directors. Local risk tolerance directs that all risks graded as 12 or above must be escalated to Division and then, once agreed, to Trust Risk Register for Director consideration. At which stage the Director or the Board as appropriate will make an assessment of its impact and management. All risks must have controls that will reduce/manage them or the Trust must consider whether the activity associated with that risk must be continued.

4.2 The level of acceptable risk is supported by a standardised grading matrix, reporting framework and staff training which directs the escalation and timely management of risk.

Operational and Divisional Risks Flowchart

Please refer to Trust Categorisation Matrix (Attachment 1) for timescales for reporting

Reporting	Repository	Process



Risk Registers – PDF/Datix: Guide

Report Title (PDF)	**What is the Risk?**		**Level of Risk**	**How are we managing the risk?**	**Evidence that it is working**	**Any Evidence that it is not working**	**What else can we do**		**Risk after actions**	**Date Last Reviewed**
Datix Field	**Description**	**Initial Level**	**Current Level**	**Controls** *(Assurance Tab – Controls – 'Controls'* ***IGNORE 'gaps in controls' fields***	**Assurance** (Assurance Tab – 'Assurance'	**Gaps in Assurance** (Assurance Tab – 'Gaps in Assurance'	**Actions**	**Action Lead**	**Target Level**	**Review date**
Requirements	Description – must identify and **describe the risk** not incident/issue (individual circumstance). Description should include: • The cause – what might trigger the risk/threat • The event – the adverse event • The impact – what will the event result in **IF>>>THEN>>>RESULTING IN** A date of origin, date of escalation (if applicable) and a proposed date for achieving the Target Level to be added to the Description field. Detailed Risk Assessment to be added as an attached document.	This is the grade of the initial risk identified (before mitigating actions).	This is the grade of the risk at the time of your report and reflects mitigation All risks scoring 12+ must be escalated to the Trust Risk Register via Division.	Controls – barriers to the risk. **Controls must be numbered in Datix.** Number each control (use brackets). **Controls must be dated in Datix** Date each control (use brackets) Controls on the <u>cause</u> may reduce the likelihood of the event. Controls on the <u>effect</u> may reduce the impact of the event. **Controls must be measurable** ie there must be an output which informs and provides assurance on the control/ management of the risk.	Assurance – evidence that the risk is under control. Assurances **to be numbered in Datix to align with numbered controls.** **Assurances must be dated in Datix** (use brackets) Assurances must be updated regularly (monthly, quarterly)to inform live / actual assurance.	Where **negative assurance** indicated, it may **require further action** to strengthen the control or other controls to be identified Any negative assurance **to be numbered in Datix to align with numbered controls.** **Negative assurance must be dated** (use brackets) Negative assurance must be updated regularly	Actions should have a named lead and should be achievable: • Specific – clear and unambiguous • Measurable – easy to evaluate • Achievable – within your resources • Realistic – within service constraints • Timely – not out-of-date or inaccurate Actions should be generated by any gaps in controls or assurance. All actions **to be numbered in Datix to align with numbered controls.**		This is the grade that the risk is expected to be managed down to.	This is the date you last updated the risk

Likelihood: 1 2 3 4 5	*Consequence:* 1 2 3 4 5	*Severity:* (1- 3) green	(4 – 6) yellow	(8 – 12) amber	(15+) 'Awaiting Divisional Approval'

Full Name:	**Designation:**
Signature:	**Date:**

1.0 Supporting Staff

1.1 Members of staff who become involved in serious or upsetting incidents, complaints or legal processes (including allegations of negligence or being inquest witnesses), can find it both stressful and traumatic. In addition, failure to support and involve staff can allow a 'blame culture' to develop. (see the Legal Services Policy OP31).

1.2 The Trust will provide immediate and on-going support to staff as appropriate. The first contact point for such support is the Line Manager who must be involved as soon as possible to address any immediate and on-going needs, to explain the options available and refer the staff member to other appropriate resources.

1.3 Staff that are experiencing difficulties associated with an event will be supported to feel able and willing to share their experience and seek support. The staff member must inform their Line Manager or may seek advice from another appropriate manager or colleague.

1.4 The staff member can approach Occupational Health for independent advice and support. The Occupational Health Department can action self-referrals and other services and can also support the staff member in seeking appropriate changes/alterations in their work environment.

1.5 The Trust has introduced Schwartz rounds as a general supportive means of exploring staff feeling and experiences of managing the emotional impact of work. This is available to all staff and the topic/subject can be volunteered by staff as a means of support.

2.0 Line Managers

2.1 As soon as is practicable following a traumatic event/experience, the line Manager must provide an opportunity for the staff members to discuss the event (debrief) and any impact on the individual. The debrief is usually informal and separate to any investigation that may be in place for the event; it has the following objectives.

- To establish whether the staff member is able to continue to practice in the short term and to identify any immediate support required by the staff member from family, friends or colleagues. Arrangements must be made by the manager for such contact to be made as soon as possible where indicated. Other considerations will include temporary re-location of work area/shift, emergency leave provision, clinical supervision, and union or counselling support.
- To provide information to the staff member about the process and the available support options, this may involve the expertise in the relevant corporate functions e.g. Governance Department, Human Resources, Occupational Health or Complaints Department.

2.2 On-going support required by staff will vary depending on the

circumstances of the event and the individual involved. It is the Line Manager's responsibility to consider, in conjunction with the staff member, any on-going support actions which will include reasonable work adjustment, training, involvement of other department expertise, internal or external support agencies.

2.3 Where health and wellbeing issues persist and on-going support is needed the line manager must complete an individual risk assessment (Refer: Workplace Health and Wellbeing Policy HR48 and refer the member of staff to the Occupational Health Department for on-going monitoring support.

2.4 Where the event involves a claim, inquest or complaint the Line Manager can engage other departments/managers to ensure that the member of staff has the specialist support they may require.

With the agreement of the staff member the Line Manager can notify the Legal Services Manager(s), Complaints Manager, Occupational Health or other support facility (external agencies) explaining the support needed. The Line Manager will allow staff the time to attend meetings or support sessions external to the Department.

3.0 Other Specialist Support

3.1 In the event of a compensation claim or inquest the Legal Services Manager(s) will provide specialist support and advice to staff involved, ensuring that the member of staff has the opportunity to provide statements of their involvement and to raise any concerns or comments he / she might have regarding the provision of evidence.

3.2 The Legal Services Manager(s) will support any member of staff during the preparation of a witness statement and the giving of evidence in court or at an inquest. The Legal Services Manager(s) will support the member of staff during meetings with Solicitors and Counsel and at legal conferences. The member of staff will be given the opportunity to have a representative supporting them throughout the claims process if they wish.

3.3 The Legal Services Manager(s) will keep the member of staff informed of the progress of a claim or inquest and advised of the outcome.

3.4 Where the member of staff is particularly distressed at being a party to a claim or inquest, the Legal Services Manager(s) will notify their Line Manager, so that they can provide the member of staff with additional support in the workplace, via Occupational Health Department or external services.

3.5 In the event of a complaint staff support is provided via the Line Manager, the Complaints Manager or the lead investigator of the complaint. The complaint may involve implementation of the Being Open Policy (OP60) or the provision of an apology to the patient or their family. The Being Open Policy (OP 60) gives guidance on the provision of an apology and the level of staff involvement and authorisation for meetings with complainants.

3.6 Support from the Occupational Health Department is available via management or self-referral by the member of staff. A confidential staff stress counselling service is available as well as voluntary cognitive therapy programmes and liaison with managers on work adjustments.

3.7 Where indicated external support will be identified which will include support groups, medical practitioner or Union/professional body engagement.

1.0 Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)

1.1 RIDDOR came into force on 1 April 1996. It requires that certain incidents, diseases and dangerous occurrences (meeting the regulation criteria) must be reported to the enforcing authority. The regulation applies to all work activities, but not to all incidents.

1.2 The Trust, through its management structure, requires Divisions, Directorates and Departments to ensure that systems and procedures are implemented ensuring compliance with RIDDOR (see Protocol 1: Reporting of Injuries, Diseases and Dangerous occurrences regulation Policy).

1.3 Managers must ensure that procedures are in place so that the reporting of work-related incidents is notified to the Health & Safety Manager without delay and that all staff are aware of the procedures to be followed.

1.4 In some very limited circumstances, where an individual has either been exposed to or contracted Covid 19 as a direct result of their work, those instances could become reportable under RIDDOR either as a Dangerous Occurrence (under Regulation 7 and Schedule 2, paragraph 10) or as a disease attributable to an occupational exposure to a biological agent (under Regulation 9 (b)). In line with guidance an internal sign off process by a Medical practitioner is applied.

1.5 For an incident to be reportable as a Dangerous Occurrence, the incident must result (or could have resulted) in the release or escape of the hazard group 3 Covid 19 virus. An example could include a phial known to contain the Covid 19 virus being smashed in a laboratory, leading to people being exposed.

1.6 For an incident to be reportable as an occupational exposure to a biological agent, the diagnosis of Covid 19 must be directly attributed to an occupational exposure. Such instances could include, for example, frontline health and social care workers (e.g. ambulance personnel, GPs, social care providers, hospital staff etc) who have been involved in providing care/ treatment to known cases of Covid 19, who subsequently develop the disease and this is reliably attributed to their work and verified by a registered medical practitioner's statement.

2.0 RIDDOR Types

OVER SEVEN DAY INJURY: An 'Over Seven Day Injury' is one which is not major but results in the injured person being away from work or unable to do their normal work for more than seven days (including non-working / rest days).

OVER 3 DAY ABSENCE: An 'Over Three Day' absence as a result of a workplace injury/ill health must be recorded in Datix but not reported as RIDDOR.

DISEASE: If a doctor notifies you that your employee suffers from a reportable work related disease this must be reported. A full list of reportable work related diseases is available from the Health

& Safety Manager c/o the Governance Department.

DANGEROUS OCCURRENCE: If something happens which does not result in a reportable injury, but which clearly might have done, then it may be a dangerous occurrence which must be reported immediately. A full list of dangerous occurrences is available from the Health & Safety Manager c/o the Governance Department.

RIDDOR - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (as amended 2013)
Reporting Flowchart

What is Reportable?	When to Report	How to Report
➢ Injuries • Death* • Major injury* • Over **7**-day injury • Major injuries to persons not at work on hospital premises or estate which result in hospital treatment** **(See Appendix1 for details)** * Covers Staff, Patients and Visitors ** Visitors, members of public	• Death, major injuries and persons injured on hospital premises – **IMMEDIATELY** • Over **7** day injuries – as soon as they go over **7** days. • *Over 3 day absences must be recorded in Datix for monitoring purposes.*	By telephone: 01902 695114 followed by Form F2508 within 5 days to **Health & Safety Manager (HSM)** By telephone: 01902 695114 followed by Form F2508 within **10** days to **HSM** Governance Department
➢ **Diseases** • **See Appendix 1 for details**	**When confirmed by Occupational Health or Medical Officer.** Followed by form F2508A	By telephone: 01902 695114 followed by Form F2508A within **5** days to **HSM** Governance Department
➢ **Dangerous Occurrences** • **See Appendix 1 for details**	• **IMMEDIATELY**	By telephone: 01902 695114 followed by Form F2508 within 5 days to **HSM** Governance Department

- **All incidents require the Trust incident form to be completed along with the RIDDOR form.**
- **Statements from those involved must be obtained and attached to the incident form.**
- **An investigation is required for every RIDDOR report.**
- **Covid-19 or Pandemic related incidents should be investigated using the Pandemic investigation form. (RIDDOR Investigation form link) - August 2020.**

Appendix 1

***Specified Injuries*: (replaces major injury list):**

- amputation of an arm, hand, finger, thumb, leg, foot or toe;
- permanent loss of sight or reduction of sight;
- crush injuries leading to internal organ damage;
- serious burns (covering more than 10% of the body, or damaging the eyes, respiratory system or other vital organs);
- scalpings (separation of skin from the head) which require hospital treatment;
- unconsciousness caused by head injury or asphyxia;
- any other injury arising from working in an enclosed space, which leads to hypothermia, heat -induced illness or requires resuscitation or admittance to hospital for more than 24 hours.

Diseases:

- carpal tunnel syndrome;
- severe cramps of the hand or forearm;
- occupational dermatitis;
- hand-arm vibration syndrome;
- occupational asthma;
- tendonitis or tenosynovitis of the hand or forearm;
- any occupational cancer;
- any disease attributed to an occupational exposure to a biological agent *including COVID-19*.

***Dangerous Occurrences* relevant to NHS**

- collapse, overturning or failure of load-bearing parts of lifts and lifting equipment
- plant or equipment coming into contact with overhead power lines;
- electrical short circuit or overload causing fire or explosion;
- any unintentional explosion, misfire, failure of demolition to cause the intended collapse, projection of material beyond a site boundary, injury caused by an explosion;
- accidental release of a biological agent likely to cause severe human illness;
- failure of industrial radiography or irradiation equipment to de-energise or return to its safe position after the intended exposure period;
- malfunction of breathing apparatus while in use or during testing immediately before use;
- collapse or partial collapse of a scaffold over five metres high;
- any building or structure under construction, alteration or demolition where over five tonnes of material falls;
- a wall or floor in a place of work;
- any false work;
- explosion or fire causing suspension of normal work for over 24 hours;
- sudden, uncontrolled release in a building of:
    - 100 kg or more of flammable liquid;
    - 10 kg of flammable liquid above its boiling point;
    - 10 kg or more of flammable gas; or
    - of 500 kg of these substances if the release is in the open air;
- sharps injury from a known contaminated source;
- accidental release of any substance which may damage health – *including COVID-19*.

The Royal Wolverhampton NHS Trust

COVID 19:
RIDDOR INVESTIGATION SHEET

When to report:
You must only make a report under RIDDOR (The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013) when:

- an unintended incident at work has led to someone's possible or actual exposure to coronavirus. This must be reported as a dangerous occurrence.
- a worker has been diagnosed as having COVID 19 and there is reasonable evidence that it was caused by exposure at work. This must be reported as a case of disease.
- a worker dies as a result of occupational exposure to coronavirus.

What to report:

Dangerous occurrences
If something happens at work which results in (or could result in) the release or escape of coronavirus you must report this as a dangerous occurrence. An example of a dangerous occurrence would be a lab worker accidentally smashing a glass vial containing coronavirus, leading to people being exposed.

Cases of disease: exposure to a biological agent
If there is reasonable evidence that someone diagnosed with COVID-19 was likely exposed because of their work you must report this as an exposure to a biological agent using the case of disease report. An example of a work-related exposure to coronavirus would be a health care professional who is diagnosed with COVID-19 after treating patients with COVID-19 with no clear other exposure.

Work related fatalities
If someone dies as a result of a work-related exposure to Covid-19 and this is confirmed as the likely cause of death by a registered medical practitioner, then you must report this as a death due to exposure to a biological agent using the 'case of disease' report form.

You must report workplace fatalities to the H&S team by the quickest practicable means without delay and send a report of that fatality within 10 days of the incident.

ALL other RIDDOR reportable incidents must be reported to the H&S Team as soon as possible and as soon as they breach 7 days followed by a written report within 10 days.

Report compiled by:		**Datix No.**		**Date of incident:**	
Department		**Directorate**		**Division**	
Description of events:					

Staff member involved:		**Actual work location if different from incident area:**	
Date first symptoms identified/Asymptomatic identified		**Date self-isolation commenced**	
Locations since symptom onset this should include the previous 14 days up to the date of going off		**Contacts since symptom onset this should include contacts for the previous 14 days up to the date of going off**	

sick* **Use separate sheet if necessary**		**sick*** **Use separate sheet if necessary**	
Was PPE provided?	YES / NO / Not required	**Which PPE Group was relevant to staff member**	A / B / C / D
List PPE used		**Areas/locations PPE used**	
Were any family members showing symptoms/diagnosed with COVID19 prior to staff member			Yes/No
Was Covid-19 known to be circulating in the community at the time of diagnosis?			
If Yes : How long before staff member, provide date if possible:			

Outcome of incident		
IP comments/review based on IP guidance for Covid19		**Date**
Occupational Health & Wellbeing comments/review		**Date**
Considering the information provided is the incident RIDDOR reportable i.e. is there a diagnosis of Covid19 and is there reasonable evidence (i.e. confirmed by medical practitioner/IP) to demonstrate occupational exposure.		Yes / No

Confirmed RIDDOR Reportable	**Medical Practitioner Signature**		**Date**
RIDDOR Reported to H&S Team		**H&S Team reported to HSE**	**Date**
Incident discussed at local Governance			**Date recorded**
Lessons learnt from incident			
Actions taken to prevent further incidents			
Signature		**Status**	
Date closed			

* The incubation period is from 1 to 14 days (median 5 days). Assessment of the clinical and epidemiological characteristics of COVID-19 cases suggests that, similar to SARS, most patients/staff will not be infectious until the onset of symptoms. In most cases, individuals are usually considered infectious while they have symptoms; how infectious individuals are, depends on the severity of their symptoms and stage of their illness.

Reporting and Investigation of Serious Incidents (SI)

1.0 Protocol Statement

1.1 This protocol directs the way in which staff are expected to respond to a serious and reportable incidents in line with National guidance from the NPSA, NHS England Serious Incident Framework (March 2015) and as well as reporting mandates from the Care Quality Commission and Clinical Commissioning Groups.

1.2 The Trust will take appropriate actions to prevent injury, ill-health and harm to patients, staff and visitors or loss and damage of NHS assets by means of timely reporting, effective investigation, and learning from all SIs and near misses.

1.3 SIs can be identified through real time or historic events e.g. incidents, complaints, serious case reviews, mortality reviews, Medical Examiner scrutiny, prevention of future death reports from Coroner, Whistle Blowing etc. Where a complaint has highlighted areas of harm/ potential harm to patients which meets the SI or Duty of Candour criteria, this protocol will be initiated to report and investigate the incident and communicate with patients, relatives and carers. Reference must be made between the circumstances of the complaint findings and the Trust categorisation matrix (levels of harm) to direct further action. Liaison will occur between the Complaints team (or the Directorate) and the Governance Department where there are grey areas.

All identified SI (where appropriate) must be reported in line with the protocol – in addition to its own specific process.

1.4 Investigations carried out under this policy are conducted for the purposes of learning to prevent recurrence. They are not inquiries into how a person died (matter for the Coroner) or to hold an individual or organisation to account since other processes exist for that purpose e.g. criminal and civil proceedings, disciplinary procedures etc.; however refer to section 7.1 below regarding the use of investigation statements. In addition, the Trust Mortality Review Policy (OP87) directs further on the review/investigating and reporting on deaths in the light of the national guidance on Learning from Deaths in the NHS.

1.5 Following the recommendation of the Public Administration Select Committee (PASC), a new Independent Patient Safety Investigation Service (IPSIS) will be established to conduct independent, expert-led investigations into patient safety incidents. The Healthcare Safety Investigation Branch (HSIB) became operational on 1st April 2017. Its purpose is to improve safety through effective and independent investigations that don't apportion blame or liability. It will be selective about the incidents it investigates to ensure optimum effectiveness and will focus on incident types that signal systemic or apparently intractable risks within the local healthcare system.

Examples include incidents that lead to high cost litigation claims, certain never events and incident types such as medication errors.

2.0 Accountability / Responsibilities

2.1 Trust Board of Directors

The Board of Directors has a responsibility to adhere to national and Commissioner reporting guidance.

2.2 Directors

Directors are responsible for appropriate sign off of SI reports to be made to external agencies (and for nominating a reporter where appropriate).

2.3 Head of Governance

The Head of Governance is accountable for the development and maintenance of this Policy and the system for reporting, recording and management of serious incidents to the Commissioners via the STEIS system.

2.4 Divisional Management Team

The Divisional Management Team - Deputy Chief Operating Officer (DCOO) and the Divisional Head of Nursing (HoNs) and Midwifery (HoM) and the Divisional Medical Directors are responsible for identifying a Divisional and RCA Lead for serious incident investigations. The Divisional Lead is responsible attending the Table Top meeting and the Management Team provide final approval of the RCA report before submission to the Commissioners.

2.5 Healthcare Governance Managers

The Healthcare Governance Managers oversee and monitor the incidents reported within Division and ensures SI are reported to STEIS and investigated within the Trust standard.

2.6 Directorate/Departmental Managers (those with management responsibility)

Directorate/Departmental Managers must take immediate actions in response to investigations into incidents /risks /claims /complaints. They must also review and if necessary re-grade incident reports generated within their managerial areas, if necessary with the involvement of the Governance Department. They will be required to investigate incidents, assess/manage/escalate risks identified, follow up actions from investigations and assess its improvement impact.

Following a serious/reportable incident Directorate/Departmental Managers responsible for the service/s in which the SI occurred will ensure the following actions are carried out -

- Prompt reporting and upward escalation of the incident identified (see serious incident flowchart below);
- A debriefing session and staff support (as appropriate);
- A concise investigation within 48 hours is completed;
- Be advised of the Executive/Divisional and RCA Lead Investigators who will be responsible for undertaking the Level 2 Comprehensive Investigation using Root Cause Analysis (in line with Investigation Flowchart);
- Attend RCA Top-top Meeting or send appropriate representation;
- Receive a draft RCA investigation report from the RCA Lead Investigator for discussion at a governance meeting, with agreement/approval/sign off from a Directorate perspective;
- Once final approval has been received from the Divisional Management Team ensure investigation actions are completed/followed up and learning shared from the event.

2.7 Heads of Department

Are responsible for the communication and implementation of this protocol (including reporting, investigation and management requirements).

2.8 Caldicott Guardian

Is a senior person responsible for protecting confidentiality of patients and service user's information. They must be kept informed of any level 1 or higher incidents in order to support the culture of learning and officer advice. Any ICO reportable incidents will be agreed with both the Caldicott guardian and SIRO.

2.9 Senior Information Risk Owner (SIRO)

The SIRO owns the Trusts overall information risk policy and risk assessment process ensuring we have a robust incident reporting process for information risks. The SIRO reports to the Trust Board and provides advice on the content of the Trust's Statement of Internal Control in respect to information risk.

2.10 All members of the Trust staff

All staff are accountable for ensuring that they are fully aware of the action / s to take in the event of a serious or reportable incident occurring, the criteria and timescale for reporting, investigation and management of such incidents (Table 1 and Flowchart A), and where to obtain assistance.

3.0 Protocol details/actions

3.1 Serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or the organisations so significant, that they warrant using additional resources to mount a comprehensive response.

3.2 There is no definitive list of events/incidents that constitute an SI and definitive lists must not be created locally as they can lead to inconsistent or inappropriate management of incidents. An SI is determined by the impact the event has had / will have upon patients, staff, visitors and the Trust. **Table 1 below sets out circumstances in which a serious incident must be declared**. Every incident must be considered on a case by case basis using the descriptions in table 1.

3.3 Where there are borderline cases and it is not clear whether or not an incident fulfils the definition of an SI; or where that decision relies on the judgement of people involved, the Trust (via a nominated individual) must engage in open and honest discussion with commissioners to agree the appropriate and proportionate response.

3.4 The outcome of an incident does not always reflect the potential severity of harm; therefore it may be appropriate for a '**near miss' to be classed as an SI** where there is a **significant existing risk of system failure or serious harm** should the incident or similar event occur again. Equally not all near misses must be reported as a serious incident. A Near Miss for IG is separately defined See protocol 2. In deciding an assessment must be made of the following risk factors:

- The likelihood of the incident occurring again if current systems and processes remain unchanged; and
- The potential for harm to staff, patients, and the organisation should the incident occur again

3.5 The SI reporting **flowchart A** below gives instructions on how to report and the timescales for response to an SI. **Table 1** sets out the circumstances in which an SI must be declared. All circumstances in the table are predicated by acts or

omissions in care which caused or contributed towards the outcome.

3.6 If there is uncertainty regarding the reporting of an SI, seek advice from your line manager or Trust on call manager as soon as possible. In determining the occurrence of such an incident the recommended approach is to err on the side of caution.

3.7 All SIs which require reporting to the CCG will be made by a nominated team member within the Governance Department (usually a Healthcare Governance Manager) and must be preceded by management approval and director notification.

3.8 All SIs must be graded using the incident Categorisation Matrix in Attachment 1. (please note where the incident is not graded red but meets the reporting criteria in Table 1 this Protocol will still apply).

3.9 Major Incidents are classified as SI and must be reported and managed in line with this protocol. For major incident guidance please refer to the Major Incident Plan located on the Intranet.

3.10 This protocol must also be read in conjunction with Media Relations Policy (OP06) which advises staff on how to communicate in the event of an SI which attracts media involvement.

3.11 All serious incidents in the NHS National Screening Programmes e.g. NHS Cancer Screening programmes must be managed in line with this protocol and in reference to the 'Managing safety incidents in NHS Screening Programmes' guidance at Managing safety incidents in NHS Screening Programmes (publishing.service.gov.uk). Further management guidance (including media dealings and help line set up) can be located from the relevant / responsible area/service within the Trust.

3.12 **Table 2** is the Information Governance calculator and is to be used to assess the level for Information Governance SI and the need to inform the Information Commissioner. Table 2c IG incident report is to be completed by the reporter of the IG incident.

3.13 In addition to Table 1, certain incidents require internal investigation under separate policies/procedures (but may not meet the requirement to be reported as SI's) These are described below.

3.13.1 C-diff events (Refer to Prevention and Control of Clostridium Difficile Diarrhoea (IP06) for NPSA modified RCA document for the investigation of C-diff.)

3.13.2 Methicillin-susceptible Staphylococcus aureus (MSSA) isolated in blood culture (Refer to Prevention and Control of Methicillin-resistant Staphylococcus aureus and vancomycin-resistant Enterococci (MRSA-VRE) and Other Antibiotic Resistant Organisms (IP 03) for the NPSA modified RCA document for the investigation of MRSA or MSSA.)

3.13.3 Incidents which are identified as hospital acquired Venous Thrombo-Embolism following clinical review. Please refer to the VTE Policy (CP 58) investigation template and guidance.

3.13.4 From the 1st December 2010 incidents of mixed sex sleeping accommodation is reportable to the unified reporting system but is not managed as a serious untoward incident. A mixed sex (sleeping) occurrence (i.e. where a decision is made to place a patient in a bed space or bay with a patient of another gender) must be reported as an incident on Datix and is reported to STEIS system via regular data return.

In addition to the individual mixed sex occurrence the number of patients affected in the bay must be recorded as a separate figure (Refer to the Same Sex Accommodation Policy (OP81). The Trust has agreement from Commissioners that investigation reports will not be required for reportable mixed sex events.

3.14 In response to the Covid 19 Pandemic NHSE/I produced guidance for NHS and Foundation Trusts as follows:
- The Principles for Infection Prevention & Control in the context of COVID-19 to reduce the risk to patients when requiring planned or emergency care in all healthcare settings and Managing Nosocomial COVID-19 Outbreaks (June 20 revised in July 20) and
- A letter 'Healthcare associated COVID-19 infections – further action' on 24th June 20 advising that all organisations are now required to do root cause analyses (RCAs) for every probable healthcare associated COVID-19 inpatient infection i.e. patients diagnosed more than 7 days after admission.

In doing this, they advise, it will be important that the organisation continues to reference the existing Serious Incident Framework to underpin the next level of investigation, if required to do so.

The Trust will undertake RCA investigations (to include an enhanced Structured Judgement Mortality review) for all such cases. The RCA reports will be reviewed by the ESERG meeting for further decision and action in line with the Serious Incident Framework.

4.0 Review of Serious Incidents

4.1 The Quality and Safety Advisory Group (QSAG) will monitor the completion of investigations and review RCA findings, lessons and action identified via a monthly summary reports.

4.2 The Quality and Safety Advisory Group (QSAG) will monitor the completion figures of outstanding/overdue actions resulting from serious and reportable incidents (by exception) and the resultant level of risk posed to the organisation.

4.3 Directorate management will review/approve all serious and reportable incident investigation reports. Directorate/department will follow up and monitor resultant investigation action plans. Lessons will be disseminated through line management, governance networks and Learning from Experience Group (LEG) (see local and organisational lesson sharing in Procedure 1).

4.4 The RCA Table Top meetings occur to ensure that SI investigation reports and action plans are comprehensive and quality assured. This is applicable to all RCAs (excluding serious falls, healthcare acquired pressure ulcers, infection outbreak and maternity incidents which are managed separately).

4.5 Actions from all serious and reportable incident investigations are uploaded onto Datix for tracking. Action reports are provided to Divisions/Directorates for local follow up at local Governance/management meetings.

5.0 Investigation and Documentation

5.1 Investigations must be conducted at a level appropriate and proportionate to the incident under review and must be focused on what can be learned to prevent future harm and not merely to conclude an incident avoidable or unavoidable.

5.2 All serious/ reportable incidents have a Level 1(Concise investigation within 48hrs) in order to provide timely findings, actions or identify issues which require further investigation, this enables the required 72 Hour Report required by Commissioners.

5.3 In some cases Level 1 will provide a complete investigation or it may be necessary to extend Level 1 enquiries or progress to a Level 2 (Comprehensive) RCA investigation.

5.4 Investigation templates are provided in Attachment 2 a (level 1 investigation) and b (level 2 investigation). Please refer to the named policies for specific templates noted in section 3.13. Prompt Cards, detailing example lines of enquiry for particular types of incidents, are available in this policy (at Attachment 2) and on the Governance intranet page for reference to RCA Investigators.

5.5 **Table 3** below gives guidance on the levels of investigation and the completion timescales. Each incident is considered based on its complexity/ severity alongside NPSA investigation guidance. A Level 1 (Concise Investigation) / 48 Hour Report is completed within 2 working days for all serious/ reportable incidents and where a level 2 (Comprehensive Investigation) is required it will be completed within 45 working days. These timescales are internally set however national timescales in force are 60 working days to Commissioners or 6 months if a level 3 (independent investigation) is indicated.

5.6 A step by step guide to the RCA process is provided in Protocol 3 below (excluding pressure ulcers, infection outbreaks, falls and maternity investigations) and a checklist for lead investigators in Protocol 4.

5.7 A RCA framework (Protocol 3) is devised to clearly identify key functions in the RCA process and define roles and levels of responsibility. This will be used as a local Standing Operational Procedure for the RCA process. To support robust RCA investigation the scope and terms of reference of the investigation are defined and agreed by the Divisional lead, the RCA lead and sometimes other stakeholders (Executive lead, Safeguarding team, CCG etc.). The scope is again reviewed for achievement at the RCA table top meeting. The SUI framework 2015 states that the needs of those affected by the SI should be of primary concern and advocates the involvement of patients/family in the investigation. To the end staff involved in the Duty of Candour process and/or investigation will enquire of the patient/representation about any specific areas of inquiry they may wish to have addressed in the investigation. Any patients/family concerns identified will form part of the RCA terms of reference where appropriate or may be directed to another appropriate process e.g. complaint/PALs.

5.8 When writing statements for incident investigations, litigation claims, coroner inquests or other proceedings it is important that standard contents and principles are adopted. Section 7 below provides statement writing guidance and templates to be used; advice and guidance can be sought from Legal Service Managers as appropriate. In the event of receiving a statement request from a requester external to the Trust, advice before responding must be sought from the Line Manager or Legal services who can direct further.

6.0 Management of Serious Incidents Involving the Police, Health and Safety Executive or CQC (Memorandum of Understanding)

6.1 Wherever possible, serious incident investigations will continue alongside criminal proceedings but this has to be considered in discussion with the police. In

exceptional cases (e.g. following formal request from the police, a Coroner or a judge) the investigation may be put on hold and this must be discussed with those agencies involved.

6.2 Incidents involving unexpected death or serious untoward harm and requiring investigation by the Police and/or the Health & Safety Executive (HSE) must be handled correctly and in the interest of fairness and justice. All patient safety incidents involving the Police or HSE must be investigated fully using existing NHS procedures (including bodies such as the MHRA, NHS England, NPSA, CQC or Coroner).

6.3 A Memorandum of Understanding is developed to direct on incidents which require Police involvement (page 7), the reporting and investigation of such incidents (page 9 & 10), the necessary liaison with the Police or other agencies (pages 11 – 13), securing and preserving evidence (page 15), sharing information (page 16 & 17) . Staff must refer to the memorandum of understanding in cases involving the Police or HSE and contact the Governance Department for advice/guidance.

6.4 CQC and HSE with support of the Local Government Association have also agreed a Memorandum of Understanding to ensure there is effective co-ordination and to assist each other in carrying out their responsibilities and functions. In determining enforcement responsibilities the primary consideration is whether the injured person is a patient/service user and whether the service provider is registered with CQC. If that is the case, the responsible authority will usually be the CQC unless the Police have primacy. The memorandum defines instances where CQC or HSE will take the lead on investigations (Annex A page 5 and 6), see exceptional criteria in Annex B and Arrangements for sharing intelligence is detailed in Annex C.

7.0 Investigation Interview and Statement Guidance

7.1 Investigation interview meetings will be documented and the information conveyed must be confirmed via a signed statement from the person being interviewed. Persons invited to an investigation interview will be informed of:

- The purpose of the interview, provided with details of the incident being investigated and reinforced that the SUI investigation is not part of a disciplinary process (however see section 7.2, 7.3)
- Time, place and length of the interview
- Who will be conducting the interview (and any others present)
- Any documentary evidence available to them during the interview
- The fact that they can bring a friend or colleague (NB confidentiality in their involvement)
- The fact that notes will be taken to inform the investigation but these will not act as a formal witness statement. Formal witness statements will be requested separately/in addition to the meeting.

7.2 All investigation statements can become part of a legal, human resource or Coronial process so these guidelines and the templates below must be followed (and advice sought from the Legal department where appropriate).

7.3 Where interviews or informal discussions are held to obtain information for an investigation, the interviewee must be informed that in the event of legal/human resource proceedings or on request of patient or the Coroner, the incident investigation report and supporting statements may be released with personal details redacted (where appropriate).

7.4 Statement writing - General rules to apply

- Write clearly (using black ink) or have it typed.
- State full name, job title and how long in post.
- Answer the specific request not what you think it is or feel it must be.
- Refer to the medical records in chronological order.
- Explain in brackets any unusual terms.
- Deal with facts not opinion unless asked to do so.
- Do not comment on actions of others.
- Write in first person (i.e. I and me).
- Use page numberings 1 of 3, 2 of 3 etc, sign and date the end of each page.
- It must be in your own words and express what you wish to say and not what anyone else says you must say.
- Contact Legal Services Manager(s) for help and advice.
- List all documents referenced in your statement e.g. case notes, policies, national standards etc.
- Check statement for accuracy, relevance, clear and concise language

7.4.1 Statement template A below is a letter format document to be used for statements to the Coroner (using the guidelines above).

7.4.2 Statement template B below is a general statement template to be used for all other statements (using the guidance above).

OP10 Protocol 2 Table 1

Serious Incident Indicators

Agency /Source	Circumstances in which a serious incident must be declared	Reporting timescale	Who to Notify (* refers to out of hours)
NHS England/CCG / CQC	**a) Acts and or omissions** occurring as part of NHS funded healthcare (including Community) **that result in**: ➢ **Unexpected** or **avoidable death** of one or more people. Including (suicide/self-inflicted death; and homicide by a person in receipt of mental health care within the recent past) ➢ **Unexpected avoidable injury** to one or more people that has **resulted in**: (i) an impairment of the sensory, motor or intellectual functions of the service user which is not likely to be temporary **, (ii) changes to the structure of a service user's body, (iii) the service user experiencing prolonged pain or prolonged psychological harm **, or (iv) the shortening of the life expectancy of the service user; ** likely to last for a continuous period of at least 28 days. ➢ **Unexpected or avoidable injury to** one or more people that requires further treatment by a healthcare professional in order to prevent the death or serious harm of a service user e.g. life-saving intervention, **major surgical / medical** intervention, **permanent harm** or will shorten life expectancy or result in **prolonged pain or psychological harm**; ➢ A scenario that **prevents or threatens to prevent the Trust's ability to continue to deliver healthcare services**, e.g. actual or potential loss of personal / organisational information **(SEE DETAIL IN SECTION F)**, damage to property, reputation or the environment **(SEE DETAIL IN SECTION D)**, or IT failure; ➢ **Safeguarding referrals** made against the trust that are **upheld by the local authority** ➢ **Actual or alleged Abuse**; sexual abuse, physical or psychological ill-treatment or acts or omissions which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where: healthcare did not take appropriate action/intervention to safeguard against such abuse occurring or where abuse is occurring during the provision of NHS funded care (including where alleged abuser is a staff member). This includes abuse that resulted (or was identified through) a Serious case review or other externally led investigation, where the delivery of NHS funded care caused or contributed towards the incident. Nosocomial Covid 19 Outbreaks must be reported	Within 2 hours of incident or knowledge of incident	**Internal** Inform Service Manager / Matron Deputy COO / Governance Manager / *On Call Manager Director / *On Call Director **NB. Notification to Patient (within 10wd) – see Duty of Candour Procedure in OP60.** **External** Following Divisional Management/Executive Director approval, Healthcare Governance Manager informs CCG and makes entry to STEIS within 2 working days, (NRLS and STEIS upload to inform CQC and NHS England)

	as a serious incident to STEIS (NHSE/I guidance June 20). **NB. NHSE/I letter to NHS/Foundation Trusts (24/6/20) states:** As part of this (ie procedures for managing Outbreaks), we are now asking all organisations to do root cause analyses (RCAs) for every probable healthcare associated COVID-19 inpatient infection i.e. patients diagnosed more than 7 days after admission. In doing this, it will be important that the organisation continues to reference the existing Serious Incident Framework to underpin the next level of investigation, if required to do so.		

NHS England/CCG / CQC	➢ Incidents that cause **widespread public concern resulting in loss of confidence in healthcare services** e.g. prolonged media coverage, major loss of confidence in a service triggering public concern about the quality of healthcare or an organisation. **(SEE DETAIL IN SECTION D)** ➢ Any incident which is **reported to or investigated by the police** must be notified to CQC via NRLS and considered against SI indicators above. ➢ 12 hour Breaches in Accident and Emergency (From Dec 14 12 hour breaches are to be reported as Serious Incidents further to DoH letter of instruction).		
NHS England/NHSI/CCG/CQC	**b) NEVER EVENTS (all Never Events are reportable regardless of level of harm)** 1. Wrong site surgery 2. Wrong implant/prosthesis **3.** Retained foreign object post-operation **(refer Table 1a below for scenario examples)** 4. Mis-selection of a strong potassium solution 5. Administration of medication by wrong route 6. Overdose of insulin due to abbreviation 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 – **Mental Health** 10. Falls from poorly restricted windows 11. Chest or neck entrapment in bedrails 12. Transfusion 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 **See Detail of Never Events Listing in Protocol 2 Appendix 1**	Within 2 hours of incident or knowledge of incident	**Internal** Inform Service Manager / Matron Deputy COO / Governance Manager / *On Call Manager Director / *On Call Director **NB. Notification to Patient (within 10wd) – see Duty of Candour Procedure in OP60.** **External** Following Divisional Management/Executive Director approval, Healthcare Governance Manager informs CCG and makes entry to STEIS within 2 working days, (NRLS and STEIS upload to inform CQC and NHS England)
CCG/NHSR	From 1st April 2017 NHSR require Trusts to report incidents that are likely to result in severe brain injury, as defined below: Babies born at term (≥37 completed weeks of gestation), following labour, with a severe brain injury diagnosed in the first seven days of life, namely babies that have one or more of the following: • Diagnosed with grade III hypoxic ischaemic encephalopathy (HIE); • Actively therapeutically cooled; • Have all three of the following signs: decreased central tone; comatose; seizures of any kind. NHS Resolution's Early Notification (EN) scheme – changes to reporting requirements from 1 April 2021 To reduce duplicate reporting, Trusts will report all eligible EN cases that meet the criteria to Healthcare Safety Investigation Branch (HSIB). Separate reporting	On the day of or within 1 working day of the case being identified/confirmed	**Internal** In hours Inform Healthcare Governance Manager/ Legal Service Manager /*On Call Manager Director/ *On Call Director **External** Legal Service managers to inform NHSR using designated form and portal within 30 days of the incident.

	to NHS Resolution has been paused and HSIB will instead report potential EN cases to NHS Resolution for further consideration from a legal perspective.		
	These reports to NHSR must be considered against the serious incident circumstances and harm triggers in this table – to indicate whether requires reporting as a serious incident to CCG.		
	d) An incident or series of incidents that prevents or threatens to prevent the organisation's ability to continue to deliver an acceptable quality of healthcare service, including (but not limited to) the following: **- Events that stop or may stop the service from running safely or properly** e.g. insufficient number of suitably qualified, skilled and experienced persons, an interruption to the supply to premises of electricity, gas, water, sewerage, where interruption lasted for **a continuous period of 24 hours**, physical damage to premises which has or is likely to have a detrimental effect on treatment or care to service users and the failure or malfunctioning of fire alarms or safety device in premises where that that failure or malfunction has lasted for **more than a continuous 24 hour period**. - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues (see IG detail in section F below); - 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 **(see further detail in section D below re MHA)** - 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)	Within 2 hours of the incident or knowledge of the incident.	**Internal** Service Manager / *On Call Manager Director / *On Call Director **NB. Where appropriate notification to Patient (within 10wd) – see Duty of Candour Procedure in OP60.** **External** Following Divisional Management/Executive Director approval, Healthcare Governance Manager informs CCG and makes entry to STEIS within 2 working days, (NRLS and STEIS upload to inform CQC and NHS England)

	e) Death or unauthorized absence of a person who is detained or liable to be detained under the Mental Health Act 1983. (Primarily pertains to secure psychiatric services however providers are to consider in terms of death or abscond of a sectioned patient and/or adverse media attention see Section A)	Within 2 hours of the incident or knowledge of the incident.	**Internal** Service Manager / *On call Manager Director / *On Call Director **NB. Notification to Patient/family/carer (within 10wd) – see Duty of Candour Procedure in OP60.** **External** Following Divisional Management/Executive Director approval, Healthcare Governance Manager informs CCG and makes entry to STEIS within 2 working days, (NRLS and STEIS upload to inform CQC and NHS England)
Information Commissioner [DoH]	**f) Information Governance** - Reports of serious incidents involving actual or potential loss of person identifiable data that will lead to identity fraud or have other significant impact on individuals. [All level 2 IG incidents are risk assessed against the SUI criteria for reporting to CCG. An incident can score a level 2 but classed as a near miss based on pre-defined criteria agreed with the Caldicott and SIRO (see Protocol 2 for criteria) .These incidents are not STEIS or ICO reportable. All remaining level 2 or more are investigated and **reported to Caldicott/ SIRO for consideration of reporting to the ICO/ HSCIC.** *See IG Incident severity table/calculator 2a and Cyber security severity calculator 2b below. Table 2c to be completed for all IG investigation reports. For all IG incidents deemed level 2 a full RCA report is to be completed. Table 2d Cyber incident reporting threshold will determine when a cyber-incident must be reported. Table 2e Data quality incident reporting thresholds will determine when a data quality must be reported. **N.B.** examples of incidents can be found in Protocol 2 Table 2a/2b examples of sensitivity factors	Within 2 hours of the incident or knowledge of the incident.	**Internal** Service Manager / SIRO / Governance Manager / Information Governance Officer / *On Call Manager Director / *On Call Director **NB. Notification to Patient (within 10wd) – see Duty of Candour Procedure in OP60.** **External** Following Divisional Management/Executive Director approval, Healthcare Governance Manager informs CCG and makes entry to STEIS within 2 working days, (NRLS and STEIS upload to inform CQC and NHS England) For Level 2 or above, following SIRO (or nominated representative) approval Information Governance Lead to report to Information Commissioner within 1 working day (using Table 2c investigation template)

Protocol 2 Appendix 1 – Never Events (Detailed Listing)

1. Wrong site surgery - An invasive procedure performed on the wrong patient or at the wrong site (eg wrong knee, eye, limb, tooth etc.). The incident is detected at any time after the start of the procedure.

N.B. the start of an invasive procedure is when a patient's anatomy begins to be permanently altered. For example, this is when the first incision is made that will scar the patient and take time to heal and recover from.

Includes: Interventions that are considered to be surgical but may be done outside a surgical environment – for example, wrong site block (including blocks for pain relief), biopsy, interventional radiology procedure, cardiology procedure, drain insertion and line insertion (eg peripherally inserted central catheter (PICC)/ Hickman lines).

Excludes:

- Removal of wrong teeth (Removal of wrong teeth was added to the list of excluded incidents in February 2021)
- removal of wrong primary (milk) teeth unless done under a general anaesthetic;
- interventions where the wrong site is selected because the patient has unknown/unexpected anatomical abnormalities; these should be documented in the patient's notes;
- wrong level spinal surgery (excluded from the current list while NHS Improvement works with the relevant professional organisations to ensure development of robust national barriers to prevent this incident);
- wrong site surgery due to incorrect laboratory reports/results or incorrect referral letters;
- contraceptive hormone implant in the wrong arm;
- From May 2019 'local anaesthetic blocks for dental procedures' is excluded from the 'wrong site surgery' category of Never Event.

2. Wrong implant/prosthesis - Placement of an implant/prosthesis different from that specified in the procedural plan, either before or during the procedure. The incident is detected any time after the implant/prosthesis is placed in the patient.

Includes:

- Implantation of an intrauterine contraceptive device different from the one in the procedural plan.

Excludes:

- placed implant/prosthesis is intentionally different from that specified in the surgical plan, based on clinical judgement at the time of the procedure
- specified implant/prosthesis is placed as planned but later found to be suboptimal
- implant/prosthesis is different from the one specified due to incorrect pre-procedural measurements or incorrect interpretation of the pre-procedural data – for example, wrong intraocular lens placed due to wrong biometry or using wrong dataset from correct biometry.

Refer to examples of never event scenarios (protocol 2, appendix 1, table 1a) below.

3. Retained foreign object post operation - Retention of a foreign object in a patient after a surgical/invasive procedure.

'Surgical/invasive procedure' includes interventional radiology, cardiology, interventions related to vaginal birth and interventions performed outside the surgical environment – for example, central line placement in ward areas.

'Foreign object' includes any items subject to a formal counting/checking process at the start of the procedure and before its completion (such as for swabs, needles, instruments and guidewires) **except** where items:

- not subject to the formal counting/checking process are inserted any time before the procedure, with the intention of removing them during the procedure but they are not removed
- subject to the counting/checking process are inserted during the procedure and then intentionally retained after its completion, with removal planned for a later time or date as clearly recorded in the patient's notes
- are known to be missing before completion of the procedure and may be inside the patient (eg screw fragments, drill bits) but action to locate and/or retrieve them is impossible or more damaging than retention.

Refer to examples of never event scenarios (Protocol 2, Appendix 1, table 1b) below.

4. Mis – selection of a strong potassium solution - Mis-selection refers to:
• when a patient is intravenously given a strong (≥10% potassium w/v (eg ≥0.1 g/mL potassium chloride, 1.3 mmol/mL potassium chloride) potassium solution rather than the intended medication.

5. Administration of medication by wrong route - The patient is given one of the following:

- intravenous chemotherapy by the intrathecal route
- oral/enteral medication or feed/flush by any parenteral route
- intravenous administration of an epidural medication that was not intended to be administered by the intravenous route*

* During the transition period for the introduction of NRFit™ devices, the 'intravenous administration of a medicine intended to be administered by the epidural route' cannot be considered a Never Event. An update will be provided when this period ends.

6. Overdose of Insulin due to abbreviations or incorrect device - Overdose refers to when:

- a patient is given a 10-fold or greater overdose of insulin because the words 'unit' or 'international units' are abbreviated; such an overdose was given in a care setting with an electronic prescribing system3
- a healthcare professional fails to use a specific insulin administration device – that is, an insulin syringe or pen is not used to measure the insulin
- a healthcare professional withdraws insulin from an insulin pen or pen refill and then administers this using a syringe and needle.

7. Overdose of methotrexate for non-cancer treatment - Overdose refers to when:

- a patient is given a dose of methotrexate, by any route, for non-cancer treatment that is more than the intended weekly dose; such an overdose was given in a care setting with an electronic prescribing system.

8. Mis–selection of high strength midazolam during conscious sedation – Mis-selection refers to when:

- a patient is given an overdose of midazolam due to the selection of a high strength preparation (5 mg/mL or 2 mg/mL) instead of the 1 mg/mL preparation, in a clinical area performing conscious sedation
- excludes clinical areas where the use of high strength midazolam is appropriate; these are generally only those performing general anaesthesia, intensive care, palliative care, or areas where its use has been formally risk-assessed in the organisation.

9. Failure to install functional collapsible shower or curtain rails – (applies to all settings providing NHS-funded mental health inpatient care)

Involves either:

- failure of collapsible curtain or shower rails to collapse when an inpatient attempts or completes a suicide;
- failure to install collapsible rails and an inpatient attempts or completes a suicide using non-collapsible rails.

10. Falls from poorly restricted window - A patient falling from a poorly restricted window (includes windows where the provider has not put a restrictor in place in accordance with guidance).

This applies to:

- windows ‘within reach’ of patients; this means windows (including the window sills) that are within reach of someone standing at floor level and that can be exited/fallen from without needing to move furniture or use tools to climb out of the window;
- windows located in facilities/areas where healthcare is provided and that patients can and do access;
- where patients deliberately or accidentally fall from a window where a fitted restrictor is damaged or disabled, but not where a patient deliberately disables a restrictor or breaks the window immediately before they fall;
- where patients can deliberately overcome a window restrictor using their hands or commonly available flat-bladed instruments as well as the ‘key’ provided.

11. Chest or Neck entrapment in bedrails – Entrapment of a patient’s chest or neck between bedrails or in the bedframe or mattress, where the bedrail dimensions or the combined bedrail, bedframe and mattress dimensions do not comply with Medicines and Healthcare products Regulatory Agency (MHRA) guidance.

12. Transfusion or transplantation of ABO-incompatible blood components or organs - Unintentional transfusion of ABO-incompatible blood components.

Excludes:

- where ABO-incompatible blood components are deliberately transfused with appropriate management.

Unintentional ABO-mismatched solid organ transplantation.

Excludes:

- situations in which clinically appropriate ABO-incompatible solid organs are deliberately transplanted.

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-compatible organ, the inadvertent transplantation of that organ without appropriate management is a Never Event.

13. Misplaced naso- or oro-gastric tubes - Misplacement of a naso- or oro-gastric tube in the pleura or respiratory tract that is not detected before starting a feed, flush or medication administration.

14. Scalding of patients - Patient scalded by water used for washing/bathing.

Excludes:

- scalds from water being used for purposes other than washing/bathing (eg from kettles).

  NB. Refer also new Covid Guidance - AIDE-MEMOIRE - Nasogastric tube (NGT) placement checks before first use in critical care settings during the COVID-19 response (13th May 2020).

15. Unintentional connection of a patient requiring oxygen to an air flowmeter

This applies when a patient who requires oxygen is connected to an air flowmeter when the intention was to connect them to an oxygen flowmeter.

Excludes:

- unintentional connection to an air cylinder instead of an oxygen cylinder as robust barriers to prevent this have not yet been identified.

Example scenarios for Never Event 2. Wrong implant/prosthesis and Never Event 3. Retained foreign object post procedure

Table 1a- Never Event 2 Wrong implant/prosthesis

Earlier definitions of the Never Event type 'wrong implant/ prosthesis' were not consistently applied with regard to wrong intraocular lenses (IOL). The examples below assist with consistent application of the current clarified definition. They are intended solely as examples of the principles of the definition, and are not a complete list of circumstances where the definition applies.

Circumstance	Does this fit the Never Event definition?
A patient attended hospital for a right phacoemulsification and IOL procedure. The surgeon – a senior trainee – discussed the risks and benefits of right cataract surgery and the target refractive outcome with the patient, who consented to the procedure with the aim of achieving an emmetropic (no distance glasses) outcome. A +20.5 dioptre (D) IOL was chosen and the IOL selection sheet was completed accordingly. At the WHO sign in the surgeon confirmed with the team he wanted a +20.5D IOL. A +20.0D IOL was presented during the time out section of the WHO checklist, which was completed by the consultant (not the surgeon), scrub nurse and operating department practitioner. The team did not identify that the lens power did not match that selected on the biometry and IOL selection sheet, and previously stated at the sign in. The senior trainee continued with surgery supervised by the consultant and a +20.0D IOL was implanted in error.	This is a Never Event. The surgeon clearly stated the surgical plan for a +20.5D IOL to the team. A different IOL was inserted.
A patient was admitted for right phacoemulsification and IOL. A toric IOL was planned to correct astigmatism. The IOL power was circled correctly on the biometry sheet and this was also correctly transcribed onto an IOL selection sheet. The operation was cancelled as the list was running late and the patient was admitted a few days later for surgery by a different consultant. This surgeon confirmed at sign in and again at time out with the surgical team that a 19D model SN6AT (toric) lens was required as detailed in the notes, but did not confirm that a toric lens was required as planned. The lens presented to the surgeon was a 19D SA60AT (non-toric) and this was opened and inserted into the patient's eye.	This is a Never Event. The surgeon stated in the surgical plan the wish to implant a certain model of lens but implanted a different model, which could not correct the astigmatism.

A patient attended hospital for a left phaocemulsification and IOL procedure. The surgeon confirmed with the patient that the aim of the procedure was emmetropia and circled a +17.5D IOL on the biometry sheet. The sheet had unexpectedly been printed in a different format, moving the data for the most commonly used IOL from where it normally appeared. This meant the wrong type of IOL was circled, an anterior chamber not a posterior chamber lens. All WHO checks were appropriately completed by the surgeon and the team, and a lens power of +17.5D was confirmed verbally by the surgeon to the team as the surgical plan. A +17.5D posterior chamber lens was inserted. At the postoperative review the patient was noted to be 3.5D hypermetropic and not emmetropic.	This is not a never event. The IOL inserted was the one stated in the surgical plan by the consultant. However, this surgical plan was wrong because the surgeon had chosen the power for a posterior chamber lens using data pertaining to an anterior chamber lens.
A patient was admitted for left phacoemulsification and IOL. The surgeon discussed the refractive aim with the patient; emmetropia was agreed and a +22D lens was circled on the biometry sheet. The IOL power was then unclearly transcribed onto an IOL selection sheet and later misread as 27D, not 22D. The surgeon confirmed the IOL as 27D to the team and all checks were completed. It was not noted that the original biometry sheet indicated a 22D IOL. A 27D lens was inserted. The patient was noted postoperatively to be myopic rather than emmetropic.	This is not a never event. The IOL inserted was that stated in the surgical plan by the consultant, but the surgical plan was based on information incorrectly transcribed from a poorly written document.

Table 1b - Never Event 3 Retained foreign object post procedure

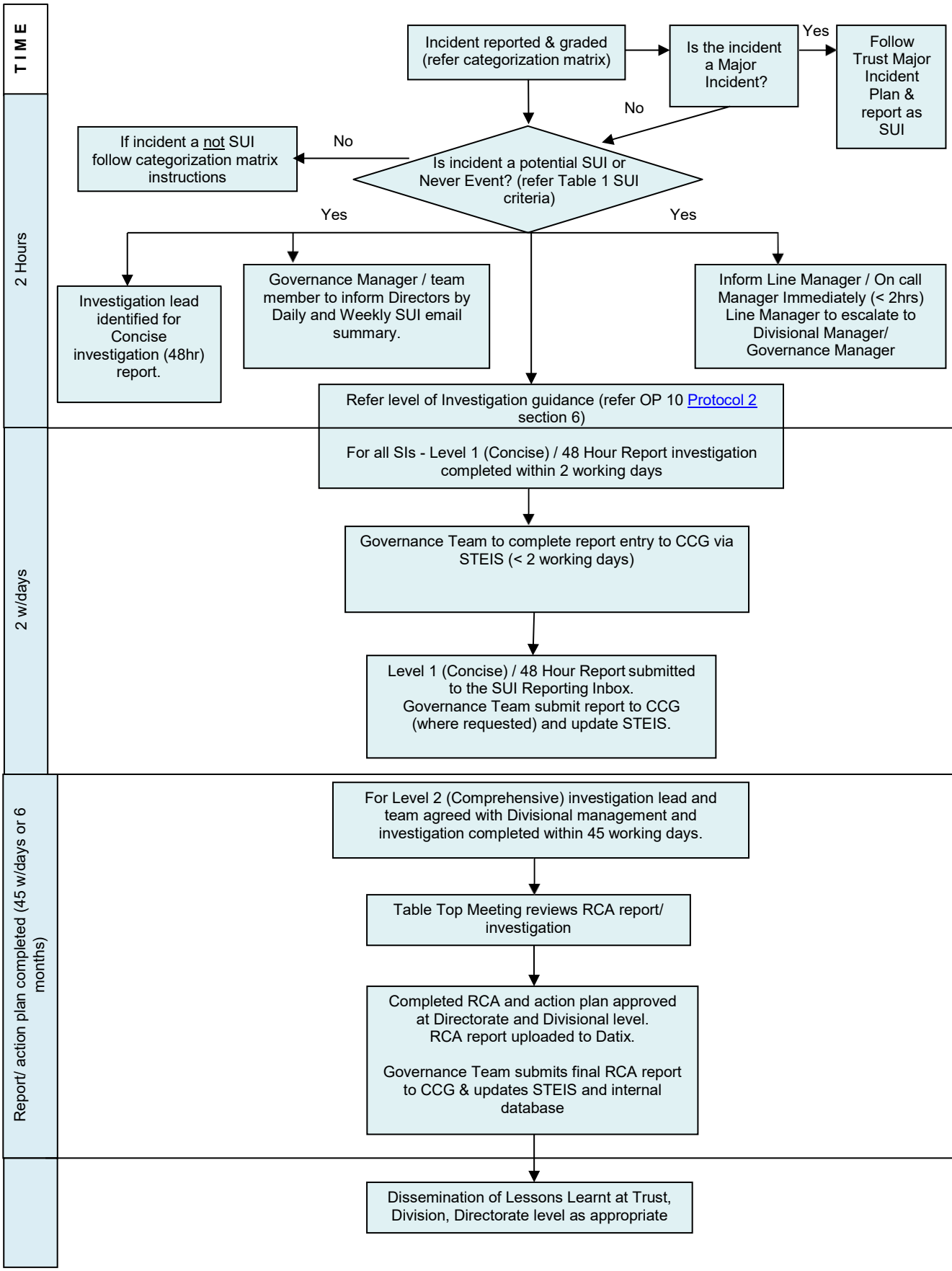
Earlier definitions of the Never Event type ‘retained foreign object post operation’ were not consistently applied. The examples below assist with consistent application of the current clarified definition. They are intended solely as examples of the principles of the definition, and are not a complete list of circumstances where the definition applies.

Note that the principles of the definition relate to items that should be subject to a formal counting or checking process at the start of the procedure and before its completion. The size of the retained foreign object and the potential for harm from the retained foreign object are irrelevant to the incident’s designation as a Never Event.

Circumstances	Does this fit the Never Event definition?
A patient underwent gynaecological surgery and a vaginal pack/vaginal tampon was intentionally left in place at the end of surgery, with removal planned for 48 hours after surgery. Unfortunately, the pack was not removed as planned and the patient was sent home with the pack still in place. She went to her GP complaining of vaginal discomfort and discharge. He examined her and found the pack.	This does not meet the definition of a Never Event as the vaginal pack was intentionally retained after the procedure. Once outside the controlled counting processes in theatre, the Never Event principle of being eminently preventable if existing guidance is followed does not apply. This incident is still likely to fit the definition of a Serious Incident and should be reported via StEIS and the NRLS, with all possible steps taken to prevent similar events in future.
A patient needed suturing after an episiotomy during a vaginal delivery. To create a clear view for the suturing procedure, three swabs were placed in the patient's vagina, to be removed as soon as suturing was complete. Only two swabs were removed. This error was realised when the swab fell out a few days after the patient and her baby went home.	This meets the definition of a Never Event. The swab was not intentionally retained. The number of swabs inserted and removed should have been counted at the time of the procedure.
A patient undergoing eye surgery as a day case had a pledget (a small swab) inserted under her eyelid an hour preoperatively to deliver topical medication. The pledget should have been removed during surgery but was not. The patient telephoned for advice about her painful eye the day after her procedure. When she returned to the unit to be examined the pledget was found and removed.	This does not meet the definition of a Never Event as the pledget was inserted outside the controlled counting processes in theatre. The Never Event principle of being eminently preventable if existing guidance is followed does not apply. This incident is still likely to fit the definition of a Serious Incident and should be reported via STEIS and the NRLS, with all possible steps taken to prevent similar events in future.
A patient undergoing eye surgery as a day case had a pledget inserted under her eyelid at the beginning of the procedure. The pledget should have been removed at the end of the surgery but was not. The patient telephoned for advice the day after her procedure because her eye was painful. When she returned to the unit to be examined the pledget was found and removed.	This meets the definition of a Never Event. The pledget was not intentionally retained and the number of pledgets inserted and removed should have been counted at the time of the procedure.

A patient had an interventional cardiology procedure using a guidewire. When the doctor tried to withdraw the guidewire, it appeared to be stuck. It was left in place so that X-rays could be taken and expert advice sought before attempting to remove it.	This does not meet the definition of a Never Event as the guidewire was known to be retained before the procedure was completed, and immediate action to retrieve it was impossible or more damaging than retention. This incident is still likely to fit the definition of a Serious Incident and should be reported via StEIS and the NRLS, with all possible steps taken to prevent similar events occurring in future. If an equipment fault is likely to be responsible, the incident should also be reported to the MHRA.
A patient had an interventional cardiology procedure using a guidewire. No problems with the procedure were noticed at the time, but an X-ray taken for another reason several days later revealed a broken-off guidewire tip lodged in a blood vessel.	This meets the definition of a Never Event as the guidewire should have been checked for completeness when it was withdrawn at the end of the procedure.

Serious Incident Reporting Flowchart A



The NHS England guidance on levels of investigation for serious incidents below.

Information in this table provides an outline of the levels of systems-based investigations recognised in the NHS (referred to as RCA investigation).				
Level	**Application**	**Product/Outcome**	**Owner**	**Timescale for completion**
Level 1 Concise internal investigation	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact investigation report which includes the essentials of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld	Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner All internal investigation must be supported by a clear investigation management plan
Level 2 Comprehensive internal investigation (this includes those with an independent element or full independent investigations commissioned by the provider)	Suited to complex issues which must be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity	
Level 3 Independent investigation	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective	Comprehensive investigation report including all elements of a credible investigation	The investigator and all members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned	6 months from the date the investigation is commissioned

	investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved		and undertaken entirely independently of the organisation whose actions and processes are being investigated.	

***Information Governance Severity Table ("IG Calculator")**

Categorising is determined by the context, scale and sensitivity. Every incident can be categorised as level:
1 – Confirmed as reportable IG SI but no need to report to ICO or DoH; or
2 – Confirmed reportable IG SI that must be reported to ICO, DoH and other central bodies.
A further category of IG SI is also possible and must be used in incident closure where it is determined that it was a near miss or the incident is found to have been mistakenly reported:
0 – Near miss/non-event - where an IG SI has been found not to have occurred or severity is reduced due to fortunate events which were not part of pre-planned controls this must be recorded as a "near miss" to enable lessons learned activities to take place and appropriate recording of the event.

BASELINE SCORE:			
Description of step	How established	**Score**	**Applicable**
Step 1 – Establish the scale of the incident (if unknown estimate max potential scale point)	Fewer than 10 individuals	0	
	11-100 Individuals	1	
	101-1000 Individuals	2	
	1001-100,000+ Individuals	3	
SENSITIVITY:			
	(B) Information readily accessible or already in the public domain or would be made available under access to information legislation e.g. Freedom of Information Act 2000	-1	
	(C) Information unlikely to identify individual(s)	-1	
	(D) Detailed information at risk e.g. clinical/care case notes, social care notes	+1	
	(E) High risk confidential information	+1	
	(F) One or more previous incidents of a similar type in the past 12 months	+1	
	(G) Failure to implement, enforce or follow appropriate organisational or technical safeguards to protect information	+1	
	(H) Likely to attract media interest and/or a complaint has been made directly to the ICO by a member of the public, another organisation or an individual	+1	
	(I) Individuals affected are likely to suffer substantial damage or distress, including significant embarrassment or detriment	+1	
	(J) Individuals affected are likely to have been placed at risk of or incurred physical harm or a clinical untoward incident	+1	
	FINAL SCORE:		
	1 or less – Level 1 IG SI (Local investigation)		
	2 or more – Level 2 IG SI (Reportable to DH, ICO and STEIS)		

All incidents will continue to be scored using the IG calculator and where they score a level 2 and above will be STEIS reported, **unless** they are a near miss as defined below. The score will be recorded on Datix, the fact it is a near miss and the rational. These incidents will continue to be locally investigated.

Near Miss Criteria

- Email sent in error to **internal Trust department** with person identifiable or sensitive data included in it. Confirmation has been received that it has been deleted.
- Email with person identifiable or sensitive data sent to correct recipient **via insecure means but it was received** as intended.
- Fax sent in error to **internal Trust department** with person identifiable or sensitive data included in it. Confirmation has been received that it has been deleted.
- Post sent to the wrong **internal Trust department** with person identifiable or sensitive data. No named contact/ not correctly labelled. Returned to sender.

- Post sent to wrong **external recipient** with person identifiable or sensitive data but retuned to Trust without opening.
- Print sent to wrong printer with person identifiable or sensitive data included in it, found by another staff member and confirmation received it has been destroyed.
- Patient list/ handover found on Trust premises by Trust staff and destroyed or handed in.
- Suspected unauthorised access - allegation cannot be proven after an audit of the record.
- Accessing a prohibited website by mistake – no impact to Trust systems (Cyber near miss).

Those below may be considered as a near miss but must be assessed by the IG manager for decision:

- Lost & Found: person identifiable or sensitive data was lost but has since been found – the caveat being as long as there isn't evidence to suggest the data has been compromised / intercepted.
- A record containing personal, sensitive information cannot be found after an extensive search and is therefore assumed to be "lost" – unless it is safeguarding record, Children's records or compliant received from data subject about missing information.
- Patient file found to have been dropped/ left unattended on Trust premises – found by another staff member.

IG Calculator Sensitivity Factor Guide

(A) No sensitive personal data (as defined by the Data Protection Act 1998) at risk nor data to which a duty of confidence is owed
Example: the data involved in the incident does not contain information that includes: • Racial or ethnic origin of data subjects • Political opinions of data subjects • Data subjects religious beliefs or other beliefs of a similar nature. Details as to whether the data subjects are members of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992. • The physical or mental health or condition of data subjects • Sexual life of data subjects • The commission or alleged commission by a data subject of any offence; or • Any proceedings for any offence committed or alleged to have been committed by a data subject, the disposal of such proceedings or the sentence of any court in such proceedings. Confidential information includes clinical records or any data that would enable someone to learn something confidential about someone that they didn't already know. Data that is neither confidential nor sensitive will be demographic data that isn't readily available in the context e.g. an individual's name in the context of who was present at a hospital on a particular day.
(B) Information readily accessible or already in the public domain or would be made available under access to information legislation e.g. Freedom of Information Act 2000
Example: the data involved in the incident is already accessible in the public authority's Publication Scheme or otherwise available on the public authority's website. This will be copies of business meeting minutes, copies of policies and procedures that may contain the name of a senior officer or members of staff responsible for signing off such material where they have an expectation that their names and job titles would be accessible. Example: non confidential information e.g. information from telephone directory which includes data items to which we do not owe a duty of confidence.
(C) Information unlikely to identify individual(s)
Example: information is likely to be limited demographic data where the address and/or name of data subjects are not included. For example: lists of postcodes within political wards Examples include soundex codes, weakly pseudonymised personal data, and Hospital ID number.
(D) Detailed information at risk e.g. clinical/care case notes , social care notes etc.
Example: Social Worker case notes, Social Care Records, Information extracted from core Social Care systems, Minutes of Safeguarding Review Meetings, Hospital discharge data details, observations of service users, clinical records etc.

(E) High risk confidential information
Example: information where disclosure has been prohibited by Order of a Court and may also include information which its disclosure/handling is governed by statutory requirements, guidance or industry practice. This may include information processed under the following, but not limited to, publications: Information classed as particularly sensitive information: Sexually Transmitted Disease (STD), rape victims, child safeguarding data which would cause considerable distress and damage if it got into the public domain.
(F) One or more previous incidents of a similar type in the past 12 months
Example: more than one incident where an email containing sensitive or confidential data identifying a living individual, has been sent to the wrong recipient. One or more incidents of Social Workers leaving their case recording books with a User of a service. One or more incident of a fax being sent to the wrong fax number or sensitive prints being left on a printer. Could include multiple incidents of the same type which have occurred within a specific department or unit or organisation. Specify within the incident details in terms of whether it is a reoccurring problem within a team, department or throughout the organisation.
(G) Failure to implement, enforce or follow appropriate organisational or technical safeguards to protect information
Example: data has been transferred onto an unencrypted USB device in breach of organisational policy and subsequently lost. Disclosure of information as a result of not complying with an organisations mobile device guardianship policy e.g. left in the car overnight. . Example: GP transferring clinical records on unencrypted CD's. Organisations must have policies in place which reduce the risk of data breaches and to ensure that avoidable risks do not occur or re-occur.
(H) Likely to attract media interest and/or a complaint has been made directly to the ICO by a member of the public, another organisation or an individual
Example: Loss of large volumes of personal identifiable data being shared between a public authority and an outsourced/commissioned provider. Disclosure of information relating to sex offenders or vulnerable adults. Where a complaint has been made to the ICO they are duty bound to investigate if a data breach has taken place. This type of incident would often receive more attention than would otherwise be the case due to the route by which the breach was raised.
(I) Individuals affected are likely to suffer substantial damage or distress, including significant embarrassment or detriment
Example: financial loss e.g. the loss of Bank Account details of service users, likely resulting in the actual loss of funds of a data subject. Substantial distress would be a level of upset, or emotional or mental pain, that goes beyond annoyance or irritation e.g. loss of entire historical record relating to a previously looked after child. Example: details of individual in witness protection program or individual who had asked for their ID to be protected.
(J) Individuals affected are likely to have been placed at risk of or incurred physical harm or a clinical untoward incident
Example: loss of personal information relating to Vulnerable Adults identifying their location, key safe details, reasons for vulnerability. Disclosure of information relating to Data Subjects located in refuge houses, Disclosure of information relating to location of offenders being rehabilitated in the community. Example: loss of the sole copy of a clinical or social care record. Information where there is no duplicate or back up in existence, so prejudicing continuity of care.

OP10 Protocol 2 Table 2b

The Royal Wolverhampton NHS Trust

Cyber Security Severity table ("Cyber incident Calculator")

The Cyber SUI category is determined by the context, scale and sensitivity. Every incident can be categorised as:

1. Level 0 or 1, a confirmed Cyber SUI but no alerting to HSCIC & DH or
2. Level 2, a confirmed Cyber SUI alerting to HSCIC & DH.

BASELINE SCORE:			
Description of step	How established	**Score**	**Applicable**
Step 1 – Establish the scale of the incident (if unknown estimate max potential scale point)	No impact: attack(s) blocked	0	
	False alarm	0	
	Individual, internal group(s), team or department affected.	1	
	Multiple departments or entire organisation affected.	2	
SENSITIVITY:			
Step 2 – Identify which sensitivity characteristics may apply and adjust the baseline scale point accordingly for **each factor identified**.	(A) A tertiary system affected which is hosted on infrastructure outside health and social care networks.	-1	
	(B) Repeat incident (previous incident within last 3 months)	+1	
	(C) Critical business system unavailable for over 4 hours	+1	
	(D) Likely to attract media interest	+1	
	(E) Confidential information release (non-personal)	+1	
	(F) Require advice on additional controls to put in place to reduce reoccurrence	+1	
	(G) Aware that other organisations have been affected	+1	
	(H) Multiple attacks detected and blocked over a period of 1 month	+1	
	FINAL SCORE:		
	1 or less – local investigation required.		
	2 or more – Level 2 IG SI (Reportable to STEIS, DH, ICO).		

Cyber incident sensitivity factors broken down

(A) A tertiary system affected which is hosted on infrastructure outside health and social care networks.
Example: a staff discount site (that does not contain personal details), an externally hosted training website, an external forum site, or an outsourced externally hosted estates management system. Does not include any key information assets (irrespective of hosting arrangements).
(B) Repeat Incident (previous incident within last 3 months)
Example: a 2nd denial of service attack occurs at an organisation within 3 months of the 1st.
(C) Critical business systems unavailable for over 24 hours
Examples of critical information systems will include electronic patients record systems, key departmental systems e.g. Theatres Management, file storage, network and telephone infrastructure, infrastructure services (active directory, dhcp, dns etc.) and critical firewalls. N.B. these can include key information assets but also encompass key infrastructure services.
(D) Likely to attract media interest
Example: any Cyber incident that leads to compromised systems within the health and social care sectors is likely to be of media interest due to increased focus on all things Cyber.
(E) Confidential information release (non-personal)
Examples: non-personal confidential information will include unabridged board meeting meetings, corporate financial planning information and planned service transformation information (restricting, closure and merger of services).
(F) Require advice on additional controls to put in place to reduce reoccurrence
Example: where a Cyber incident has occurred and appropriate physical, administrative or technical control(s) (e.g. patching, a system which is utilised by several organisations) may well be available however the organisation may need consultation and resources to action them.
(G) Aware that other organisations have been affected.
Example: a shared infrastructure Cyber incident (e.g. a local healthcare economy COIN) , a mass malicious spam which is known to have effected multiple organisations or a social engineering attack with telephone callers impersonating the local IT section in order for users to take compromising actions reported at multiple organisations.
(H) Multiple attacks detected and blocked over a period of 1 month.
Example: a significant number of unknown source IP's trying to access a known destination and service blocked by a firewall/IPS. Malicious and repeated spam emails being blocked at an email gateway. The volume of attempts/attacks reporting threshold must be a reflective of the type and nature organisation and there is no desire to report per event.

Although the primary factors for assessing the severity level are the criticality and scale of the incident, for example the potential for impact on confidentiality, integrity or availability. If more information becomes available, post incident investigation the Cyber SUI level must be re-assessed.

Please note: onversely, when targeted systems are protected e.g. by an Intrusion Prevention System, so that no services are affected the sensitivity factors will reflect that the risk is low.

All Cyber SUIs entered onto the IG Toolkit Incident Reporting Tool and confirmed as severity level 2, will trigger an automated notification email to the DH and HSCIC.

There are 2 factors which influence the severity of a Cyber SUI – Scale and Sensitivity. The IG Incident reporting tool works on the following basis when calculating the severity of an incident:

Scale Factors

Whilst any Cyber SUI is potentially a very serious matter, the scale is clearly an important factor. The scale provides the base categorisation level of an incident, which will be modified by a range of sensitivity factors.

*See context level help

A further category of Cyber SUI is also possible and must be used in incident closure where it is determined that it was a near miss or the incident is found to have been mistakenly reported:

0. No impact: attack blocked, and
0. False alarm

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

Sensitivity Factors

Sensitivity in this context may cover a wide range of different considerations and each incident may have a range of characteristics, some of which may raise the categorisation of an incident and some of which may lower it. The same incident may have characteristics that do both, potentially cancelling each other out. For the purpose of Cyber SUIs sensitivity factors may be:
i. Low – reduces the base categorization
ii. High – increases the base categorisation

OP10 Protocol 2 Table 2c

The Royal Wolverhampton NHS
NHS Trust

INFORMATION GOVERNANCE INCIDENT REPORT

To be completed by the Investigating Officer or their nominee for all IG incidents (including SUIs) and attached to Datix. ***Please note that any emails or other documents prepared in connection with this incident must be added as documentation onto Datix. Circulation of such documents must be restricted to those directly involved in investigating the incident. Please do not reference any data subjects by name in this report.***

Report completed by (name, job title)	
Datix number	
Date of incident	
Time of Incident	
Location of incident	
Breach type	Choose an item.
Clinical Patient Safety aspect (Tick) (Provide details if applicable)	☒

1 Description of data lost, stolen, released or corrupted (*include examples of type of data and volumes of records affected)*	
The number of **patients**/service users/staff (individual data subjects) involved	
The number of **records** involved.	
The format of the records (delete as appropriate)	Paper/ Digital
If digital format, whether encrypted or not.	Yes/ No
The sensitivity of the data involved	Choose an item.
Whether the IG SUI is in the public domain.	Yes/No
Whether the media (press etc.) are involved or there is a potential for media interest.	Yes/No
Whether the IG SUI will damage the reputation of an individual, a work-team, an organisation	Yes/No
Whether there are legal implications to be considered.	Yes/No
Initial assessment of the severity level of the IG SUI (see calculator for scoring criteria)	

2 Circumstances of the loss, theft, release or corruption (*include timing of events; location; IT hardware and applications involved; details of actions taken to date e.g. anyone who has been contacted in relation to the incident)* DO NOT CONTACT INDIVIDUALS WHOSE PERSONAL DATA HAS BEEN COMPROMISED UNTIL ADVISED INVESTIGATION LEAD

3 Details of any persons and regulatory bodies who have/may need to be informed	
Caldicott Guardian	Provide date
Senior Information Risk Owner	Provide date
Chief Executive / Director	Provide date and name
Data subjects	Provide date and name
Police, Counter Fraud Branch, etc.	Provide date and details
Other	Provide date and details

4 Assessment of any related policies, procedures or guidance which have been breached or wider issues *(provide copies of any local guidelines or procedures which have not been followed)*

5 Remedial action taken or recommended to prevent a further occurrence e.g. has the data custodian completed the University's Protecting Information course? *(include name of action owner and target dates for completion where appropriate)*
Reason for incident:

OP10 Protocol 2 Table 2d – Cyber reporting thresholds

		Where the effect is:	
		No impact/damage/corruption	Positive damage/corruption
MALICIOUS CODE	High number of any virus on one specific day	>50	>25
	Multiple Instances of Specific Virus Detected in a 5 working day period	>50	>25
	Loss of malicious code detection management system and/or ability to monitor the estate for malicious threats	>48 hours	>4 hours
HACKING ATTEMPTS	Firewalls or external website receives multiple attacks from the same source IP address	Non-reportable	>0 or where a 2nd significant denial of service attack with no damage occurs with 1 months of the 1st.
	Hacking Firewalls or external website receives multiple attacks from the different IP address on one specific day	Non-reportable	>0 or where a 2nd significant denial of service attack with no damage occurs with 1 months of the 1st.
	Deliberate or accidental defacement of Trust web site	Non-reportable	>0
	Spoof website - Trust or third party business critical	>0	>0
System Outage causing data loss/corruption/unavailability	Dos Denial of Service - External or internal excessive packets/emails received in any time period affecting multiple users	Non-reportable	>101 individuals or where a 2nd no impact denial of service attack occurs with 3 months of the 1st.
	Loss of Internet and/or N3 service provision resulting in lack of access to external third party hosted business critical websites including NHSMail	>24 hours	>4 hours
	Critical business systems unavailable	>24 hours	>4 hours
	Loss of patch management system and/or ability to monitor the estate for patch status	>72 hours	>4 hours
	Loss of web filtering and/or gateway anti virus scanning services	>24 hours	>4 hours
	Compromise of Trust Facebook/Twitter accounts	Non-reportable	>0

	Lack of immediate backup availability when	Non-reportable	>24 hours
	restoring data/systems due to loss and/or corruption		
	Compromise of Trust WiFi provision resulting in shut down of WiFi service provision	Non-reportable	>4 hours
Phishing Emails	Phishing emails from same sender on one specific day	>100	>25
	Phishing emails from multiple senders in a 5 working day period	>500	>100

OP10 Protocol 2 Table 2e – Data quality reporting thresholds

The Royal Wolverhampton NHS NHS Trust

Type of Incident	Description	Reporting Criteria based on an individual Number of Incidents within same ward / department by one employee	Reporting Criteria for department Total Number of Incidents within same ward / department	Timeframe	Severity
Incorrect Admission, Transfer or Discharge dates	Where the dates recorded on PAS/iPM for an inpatient spell are incorrect	5 occasions within 3 month period	5 occasions within 1 month period	3 months	
Incorrect Admission Method/Source	Where the admission method or source recorded on PAS/iPM for an inpatient spell are incorrect	5 occasions within 3 month period	10 occasions within 3 month period	3 months	
Incorrect Discharge Method/Destination	Where the discharge method or destination recorded on PAS/iPM for an inpatient spell are incorrect	5 occasions within 3 month period	10 occasions within 3 month period	3 months	
Deceased Date incorrectly recorded	Where a patient's deceased date is not recorded following a death whilst admitted or entered inaccurately	3 occasions within 1 month period	5 occasions within 1 month period	1 month	
Misfiled Patient Information (physical notes/scanned)	Where patient identifiable documentation has been incorrectly filed and/or scanned onto Portal	1	1	N/A	
E-discharge incorrect (Not Draft)	Where incorrect admission/discharge dates have been entered onto E-discharge (final version)	3 occasions within 1 month period	5 occasions within 1 month period	3 months	
Incorrect Admission Speciality/Ward	Where patients are admitted under an invalid/incorrect speciality e.g. Male admitted to Gynae	3 occasions within 1 month period	5 occasions within 1 month period	1 month	
Missing Spell	Where an inpatient spell has been missed	1	1	N/A	
Timeliness related (admissions/discharges/op attendances entered late)	When an admission or discharge is entered over 24 hours late	N/A	10 occasions within 3 month period	3 months	
Missing Patient Details/Duplicate Registrations		10 occasions within 3 month period	20 occasions within 3 month period	3 months	
Galaxy - Incorrect Hospital Numbers	When a patient has been admitted using the Theatre system with an invalid hospital number that potentially relates to another patient	1	1	N/A	
Miscellaneous		Case by Case Basis	Case by Case Basis	N/A	

STATEMENT TEMPLATE A

Enter address here if not using hospital headed notepaper.

Add telephone contact e.g. home/work/mobile

Your Ref. (Quote coroner's reference)

Date

Enter name of Coroner
H.M. Coroner Office
Smethwick Council House
High Street
Smethwick
West Midlands
B66 3NT

Dear Enter name of Coroner

Inquest – – deceased

Enter details of your full name and job title at the time in question and say how long you have been in post doing that job.

Fill in details of letter. This must include your knowledge of the patient and how you were involved in his or her treatment and care by reference to the medical records. The Legal Service Managers will assist you but we cannot tell you what you must say because that is a matter between yourself and the coroner. Where less common medical terms are used, it is both polite and helpful to the coroner to explain what is meant in brackets after the word in question.

You may wish to end your letter by expressing condolences to the family but this has to be your personal choice. It is polite to add that if you can help the coroner further you will be happy to do so.

Go on to further pages if necessary. Please mark every page with a number in the bottom right hand corner.

Yours sincerely

Sign here

Enter name and designation

STATEMENT TEMPLATE B

Statement Author name:

Occupation/Job

Title/Designation

Professional address

Subject of Statement (e.g. patient/client X at what

incident/location) Date Statement produced

Introduction

Each point – new paragraph
This statement is based on.. (e.g. personal recollection) I have been involved in the care of…
I am responding to allegations of..

Narrative

Explain the event incident or accident in chronological order Use subheadings and new paragraphs
Describe informal meeting/phone calls where relevant
List all documents referenced in your statement e.g. case notes, policies, national standards etc

Summary/Closing statements

Recap main points and avoid adding new information or comments

Include 'Statement of truth' – This statement is true to the best of my knowledge and belief.

Your

signature

Date of

signature

RCA process for Serious Incidents (SI) – step by step

[Excluding pressure ulcers, falls and maternity investigations]

Timescale	Who	Step	Further information	Resources	Failure impact
As soon as possible after awareness of incident. See timescales in OP10 (Risk Management Policy).	**Any staff** **Directorate staff**	Report incident (actual or potential SI) onto Datix Escalate to Directorate Management and Governance Team.		OP10 SUI Reporting inbox Datix	
	Governance Team	Seek agreement from Directorate and Divisional Management that the incident is STEIS-reportable.		SI list Never Event list	
Within **48 hours** of confirming the incident is a SI	**Governance Team**	Report incident to STEIS and CCG and instruct 48 Hour Report Lead (as identified by Directorate) by email to complete 48 Hour Report.	Email includes a reminder about Duty of Candour.	RCA Report Template	For failure to report incident to STEIS/ CCG on time: Fine of **£250**
	48 Hour Report Lead	Completes 48 Hour Report, using supporting information (e.g. medical records, initial comments from staff)	48 Hour Report Lead is from within the Directorate (usually a Senior Sister, Matron, Consultant or Directorate Manager)	Level 1 RCA Report Template	

	Directorate Management	Approve 48 Hour Report	Any representative from management trio, if not all. N.B. 48 Hour Report does not require Divisional approval		
By **midday** on the date indicated in email from Governance	**48 Hour Report Lead**	Submit approved 48 Hour Report to SUI Reporting Inbox			
Within **48 hours** of Trust reporting incident to STEIS/ CCG	**Governance Team**	Submits 48 Hour Report to CCG (where requested) and updates STEIS			For failure to submit 48 Hour Report on time: Fine of **£250**

Within **10 working days** of incident being reported to STEIS/ CCG	**Directorate representative** Directorate to identify the most suitable person to speak to the patient/ family. This will usually be a senior clinician involved in the patient's care (e.g. Consultant or Matron) or a manager within the Directorate as appropriate, depending on the nature of the incident.	Undertake **Duty of Candour (Element 1 - notification)** Element 1 involves: Communication with patient, or relatives/ representatives to advise that: - the incident has occurred and offer an apology - an internal investigation is taking place - the patient/ representative(s) are entitled to know the outcome of the investigation when available and agree how they will be kept informed - Staff are to enquire of the patient/representation about any specific areas of inquiry they may wish to have addressed in the investigation.	The Datix record must be updated with details of the communication (e.g. copy letter, file note following meeting etc.) Alternatively the communication/ conversation can be recorded in the patient medical records, and Datix should state where this can be found.	OP60 Being Open Staff Information Leaflets: - Being Open - Duty of Candour Datix	For failure to comply with Duty of Candour: Fine of the cost of the episode of care up to max. **£10,000**
	Governance Team	Ask Divisional Management to nominate: - RCA Investigation Lead - Supporting Investigator (if applicable) - Divisional Lead			

	Governance Team	Email RCA Investigation Lead (and Supporting Investigator) advising of process and timescales, enclosing copy of 48 Hour Report and any other information available.	Target 45 (max 60) working days to complete the investigation process, to include Table Top Scrutiny Meeting, Directorate and Divisional approval		
	RCA Lead Investigator (and Supporting Investigator if applicable)	Agree investigation scope/ terms of reference with Divisional Lead Conduct investigation and prepare draft RCA Report	Seek any additional information required (e.g. PM report, interviews with key staff)	Level 2 RCA Report Template OP10 RCA supporting tools (Governance intranet page)	
Approximately **three to four weeks** into investigation	**RCA Lead Investigator** (and Supporting Investigator) **Executive Lead (optional)** **Divisional Lead (Chair)** **Directorate representative(s)** **Governance**	**Table Top Meeting** takes place	For all serious incidents *(excluding pressure ulcers, slips/trips/falls and maternity incidents).* These meetings enable an Executive Director, Directorate and Division to scrutinise the draft or partial RCA Report and the findings so far, whilst gaining assurance that all appropriate channels have been investigated. Attendees may make suggestions for other areas to be considered/ investigated before the report is finalised for submission to the CCG.		

	representative(s) **Any specialist staff as requested by RCA Lead Investigator**				
	RCA Lead Investigator (and Supporting Investigator)	Complete/ finalise investigation report and action plan and submit to Governance Team (via RCA mailbox).	Incorporate any suggestions or lines of enquiry identified at the Table Top Scrutiny Meeting.		
	Governance Team	Send final report to Directorate Management team for review and approval.	Any queries or suggested amendments by Directorate to be forwarded to RCA Lead Investigator for information or agreement.		
	Directorate Management Team	Ensure review and approval of RCA report and action plan.	Discussion and approval must be minuted. This is usually at a Directorate Governance meeting, but in some instances approval may be granted by the Directorate Management Team outside of this forum to comply with CCG timescales. In this case, the approved RCA report must be taken to the next Directorate Governance meeting for discussion and minuting.		

	Directorate Management Team	Attend (or send representative) Divisional management team meeting to present final report and action plan for Divisional approval.	Approval will be at a minuted Divisional management forum (e.g. Governance/ Core/ Team meeting) If not finally approved by Divisional Management, Healthcare Governance Managers will advise the RCA Lead Investigator of any changes/ additions required.		
Within **target 45 (max 60) working days** of incident being reported to STEIS/ CCG	**Governance Team**	Finalise RCA Report and submit (redacted version) to CCG requesting closure. Update STEIS.	Ensure that Directorate and Divisional approval dates are included on front page. Redact report to remove any personal identifiable information.		For failure to submit RCA to CCG on time: Fine of **£250** (or **£5000** for Never Events)
	Governance Team	Email Directorate Management Team (cc Governance Officer) to advise re timescales/ deadline for Duty of Candour (Element 2).	Usually undertaken by SI Lead Officer		

Within **10 working days** of the final RCA Report being submitted to CCG	**Directorate representative** Directorate to identify the most suitable person to speak to the patient/ family. This will usually be a senior clinician involved in the patient's care (e.g. Consultant or Matron) or a manager within the Directorate as appropriate, depending on the nature of the incident.	Undertake **Duty of Candour (Element 2 – share outcome of investigation)** Element 2 involves: Communication with patient, or relatives/ representatives to advise that the investigation has concluded and offer to share the outcome (unless they have previously indicated that they do not desire this).	Communication to take place in writing or verbally. You are not required to send a copy of the RCA report, unless specifically requested by the patient/representative(s) The Datix record must be updated with details of the communication (e.g. copy letter, file note following meeting etc.) Alternatively the communication/ conversation can be recorded in the patient medical records, and Datix should state where this can be found.		
	Governance Team	Field and process any CCG queries prior to closure			

De-escalation of SIs

If at any point in the RCA investigation process it becomes apparent that the facts do not support the incident still being classified as a Serious Incident (e.g. if a post mortem report indicates an unrelated/ unavoidable cause of death), the Governance Team should be notified. A clear rationale for de-escalation must be provided. The Governance Team will seek Divisional Management Team and ESERG approval to request a formal de-escalation by the CCG.

Any further queries from the CCG will be co-ordinated by the Governance Team. The incident should continue to be treated as a SI until formal confirmation of de-escalation is received. It is likely that the investigation will still need to be

completed to capture any learning or actions from issues arising. Duty of Candour may also still be applicable – the Governance Team can advise as necessary.

Checklist for RCA Lead Investigators

Datix no:		Divisional Lead:	
STEIS no:		Executive Lead:	
Patient no:		Type of incident:	
Draft report due to Governance:			
Table Top Meeting and Executive Review dates to be confirmed as per schedule			

Timescale	**Process**	**Further information**
ASAP after accepting request to investigate	Identify and gather information required, e.g.: - Datix incident record - 48 hour initial report - Clinical notes (via Portal or paper records) - Witness Statements - Relevant Policies/ Procedures - Post-mortem Report (if applicable)	This list is not exhaustive; requirements may change as the investigation progresses. Forward copies of statements to RCA mailbox.
ASAP after accepting request to investigate	Agree scope/ terms of reference of investigation with Divisional Lead	Advise Governance dept via RCA mailbox
Investigation underway	Identify any additional staff/ specialists to be invited to Table Top Meeting	Advise Governance dept via RCA mailbox
By deadline stated	Submit draft RCA report to Governance	Via RCA mailbox
Approx. 3-4 weeks into investigation	Present draft RCA at Table Top Meeting chaired by Divisional Lead	Executive Lead may attend (optional)
After Table Top Meeting	Follow up any further lines of enquiry/ update draft report as agreed at Table Top Meeting	Submit updated report to Governance via RCA mailbox
During Directorate/ Divisional sign off process	Respond to any queries from Directorate and Division and update draft RCA if necessary	Submit updated report to Governance via RCA mailbox
Approx. 6 weeks into investigation	Present RCA report to Executive Lead	And/ or Divisional Lead to attend
After Executive Review	Follow up any further lines of enquiry/ update draft report as required by Executive Lead.	
After Executive Review	Submit final report to Governance and confirm Executive approval	Via RCA mailbox