Trust Policy

NHS Worcestershire Acute Hospitals NHS Trust

Investigating Serious Incidents Policy

Department / Service:	Clinical Governance	
Originator:	Katherine Leach	Patient Safety and Risk Manager
Accountable Director:	Vicky Morris	Chief Nursing Officer
Approved by: **Ratified by:** **Endorsed by:**	Serious Incident Review and Learning Group: 17.05.18 Clinical Governance Group: Quality Governance Committee:	
Date Endorsed:	June 2018	
Review Date: **This is the most current document and is to be used until a revised version is in place**	3rd January 2021	
Target Organisation(s):	Worcestershire Acute Hospitals NHS Trust	
Target Departments:	All	
Target staff categories:	All	

Purpose of this document:

This policy describes the management arrangements for the consistent investigation of incidents and the subsequent dissemination of local and organisational learning and improvement.

It describes a proportional approach to the level of investigation required and differentiates between concise and comprehensive investigations.

It also links to the related polices that cover Being open / Duty of Candour, supporting staff following an incident or complaint and staff management. The investigation of a complaint or claim will follow the processes set out in this policy and reference should be made to the complaint and claims policies for further detail specific to those areas.

Key amendments to this Document:

Date	Amendment	By:
3rd July 2020	Document extended due to COVID 19 period	Dee Johnson
May/ June 2018	Amendment to flowchart Addition of information informing staff who to contact in the event of an SI Addition of information regarding involving palliative care team where an incident is likely to lead to the death of a patient Addition of declarations of interest for IOs added to policy Addition of falls flowchart and ICR in Appendix Removal of Incident Decision Tree and insertion of Just Culture Guide	Katherine Leach

December 2017	Inclusion of - ensuring staff whose information is quoted investigations review the report before it is signed off - Coroner's inquests: where the coroner has raised concerns on his behalf or behalf of the family, an ICR will be submitted to the SIR&LG to identify whether a full investigation is necessary - Downgrading incidents, and when this can be done - Ensuring any changes to the report at divisional or corporate level are shared and agreed with the IO - Specific timeframes throughout the process	Katherine Leach
June 2017	Removal of complaints and claims process in title and main body but making clear that the investigations of complaints and claims are linked. Addition of SI Framework guidance Changes to the speed in which Serious Incidents are reported externally and flowchart amended to reflect this. Removal of the terminology 'Divisional Comprehensive Investigations' and replaced with the same terminology in the SI Framework: Level 1 Concise or Level 2 Comprehensive (which can be used for SI investigations or Divisional Investigations. All RCA tools removed due to a RCA toolkit design Addition of RIDDOR reporting for patient harm and flow chart for RIDDOR reporting falls (Appendix 5 and 6) Making the investigating officer the lead for the action plan until it is completed and uploading the evidence onto DATIX.	Katherine Leach
November 2016	To incorporate changes made by the new Concerns and Complaints Policy & Procedure.	Tessa Mitchell
August 2016	Review of Policy to supplement the Organisational Pathway format Addition of Medicines Safety Officer and Medicines Optimisation Committee	LA Wood C. Rawlings
September 2015	Appendices 9 and 10 added to document	C Rawlings
April 2015	Name change of document from 'Investigation, analysis, learning and change policy' to 'Investigating incidents, complaints and claims policy'	C Rawlings
Nov 2014	Revision to focus on the investigation process as applied to incidents and complaints. The improvement process is now covered in the Quality Strategy. Differentiation between concise and comprehensive investigation clarified. Sis to be investigated by trained staff only – when RCA training is completed	C. Rawlings
Jan - May 12	The improvement process has been changed to the IHI improvement model to provide a single model of improvement for staff. Analysis section revised to reflect new process	C. Rawlings
June 09	First revision includes changes made to allow for: the new operational management structure and creation of two clinical Divisions - Changes to the Trust's committee structure	C. Rawlings
Oct 08	Revisions made from consultation	C. Rawlings
Oct 08	Document created	C. Rawlings

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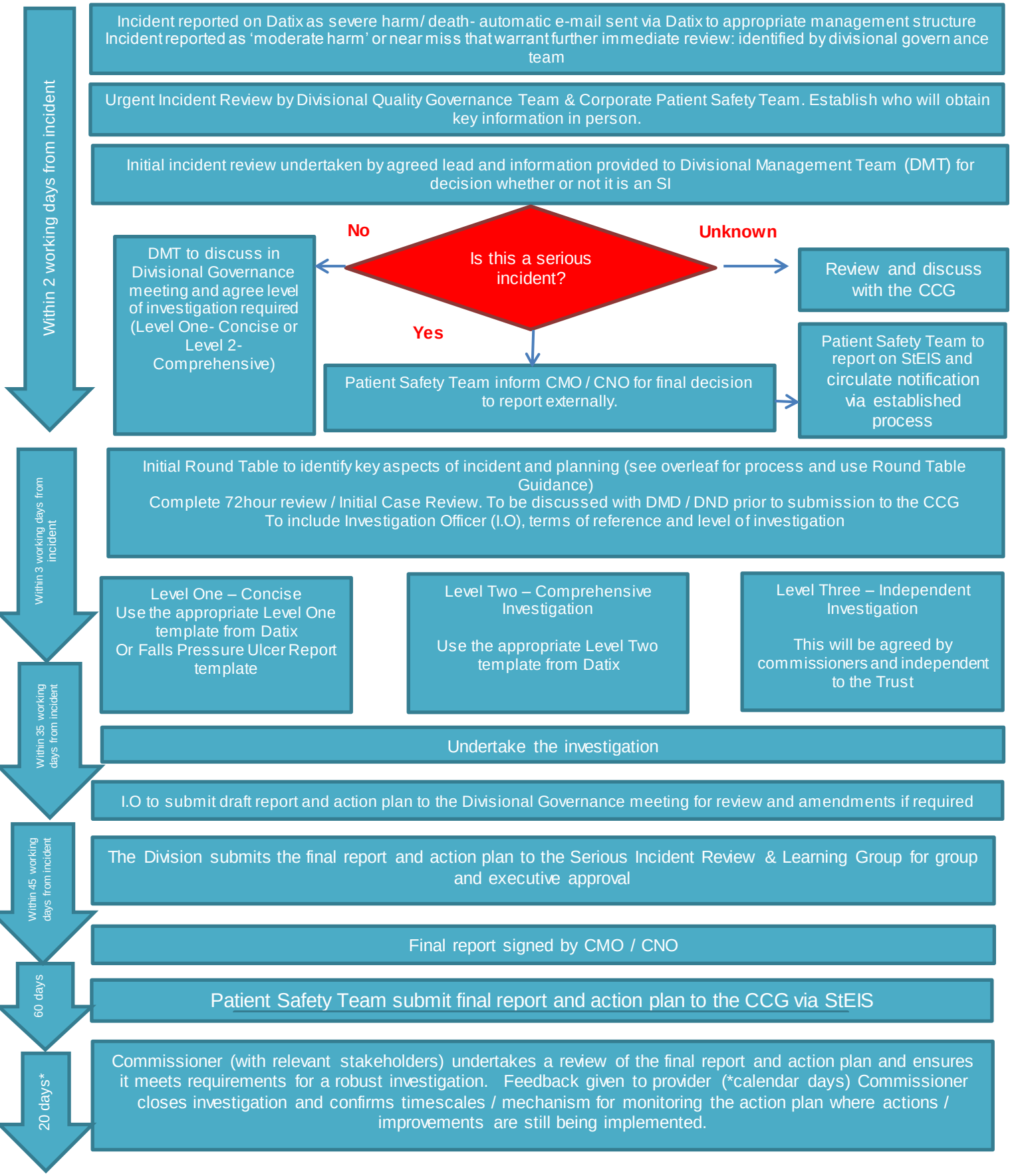
Internal Serious Incident Management Process- FLOWCHART. See page 14 for full information.



ROUND TABLE PROCESS

1. Introduction

A clinical or non-clinical error that results in an incident, complaint or claim, is rarely caused wilfully. It is not in itself, evidence of carelessness, neglect or a failure to carry out a duty of care. Incidents are often caused by a number of factors including, process problems, systemic failings, human error, individual behaviour or a lack of knowledge or skills. Learning from such incidents can only take place when they are reported and investigated in a positive, open and structured way.

It is important for the organisation to support effective learning from incidents, complaints or claims. The investigator needs to identify the direct, root and contributory causes to understand what can be improved and ensure that learning can be translated into changes in practice and procedures to improve the safety of patients and staff and the quality of services provided.

The statutory Duty of Candour places a responsibility on providers of healthcare to be open with patients when things go wrong. A suitable investigation that includes the patient's own questions and identifies the likely causes, contributory factors and what will be done to reduce the likelihood of a similar incident recurring is an essential part of the Duty.

The aims of this policy follow those of the NHS SI Framework and are:

- To ensure that an appropriate and proportional level of investigation is undertaken in relation to the severity or potential severity of the event
- To ensure that staff are appropriately trained in investigation techniques
- To ensure organisational learning and continuous improvement
- To promote a fair and open culture
- To maximise the safety and satisfaction of affected service users, carers and stakeholders
- To enable staff to participate, and effect change, in practices and procedures.

This policy should be read in conjunction with the following key documents:

- Risk Management Strategy
- Incident Reporting Policy
- Concerns and Complaints Policy and Procedure
- Being Open (Duty of Candour) Policy
- Claims Management Policy
- Health and Safety Policy

2. Scope of the Policy

This policy applies to all serious incidents, and incidents that are not deemed to be externally reportable but require further investigation by the divisional teams (clinical and non-clinical), and any other circumstances where investigations need to take place (for example complaints and claims).

This Policy applies to all areas and all employees of the Trust, including individuals employed by a third party such as internal contractors, external contractors, voluntary workers, students, locums or as agency staff.

3. Definitions

3.1 Incident

Any untoward, unplanned or unwanted event or circumstance that caused harm, damage or loss of service affecting patients, staff, contractors, visitors, members of the public or property.

3.2 Patient Safety Incident
Any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care. (NPSA).

3.3 Accident
An ***Accident*** is an unplanned event, other than a clinical procedure, that results in injury or ill health to people or damage/loss to property, plant, materials or the environment.

3.4 Near Miss
Any untoward, unplanned or unwanted event or circumstance that could have led to harm, damage or loss of service but was prevented

3.5 Hazard
A situation/factor that is known or has the potential to cause harm or make an incident more likely to happen.

3.6 Serious Incident (SI)
Serious Incidents (SIs) are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. These are reportable to external stakeholders and are further defined in Appendix 1.

Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

The occurrence of a serious incident may demonstrate weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.

Only an Executive Director or the Associate Medical Director for Patient Safety & Clinical Effectiveness can make the final decision to designate an incident as either an externally reportable serious incident and therefore requiring an internal comprehensive review.

3.7 Never Event
Never Events are a particular type of serious incident that meet all the following criteria:

- They are wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers.
- Each Never Event type has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a Never Event.
- There is evidence that the category of Never Event has occurred in the past, for example through reports to the National Reporting and Learning System (NRLS), and a risk of recurrence remains.
- Occurrence of the Never Event is easily recognised and clearly defined – this requirement helps minimise disputes around classification, and ensures focus on learning and improving patient safety.

3.8 SUDIC (sudden unexpected death in childhood)
The death of any patient under the age of 18. These must be reported on Datix regardless of whether the death was expected or unexpected. These will then be reviewed and considered as potential SIs.

3.9 Information Security / Confidentiality
Any breach of information security including the confidentiality, integrity or availability of data (both hard copy and electronic including clinical and non-clinical data).

3.10 Inquest
A judicial inquiry into any case of sudden or violent death co-ordinated via HM Coroner's Office

3.11 Claim
A claim for compensation and/or clinical negligence or any other reason made against the Trust by or on behalf of a patient, or a member of staff.

3.12 Complaint
A complaint is an expression of dissatisfaction or perceived grievance / injustice which can be made verbally or in writing to any member of staff. This should as far as practically possible be made within 12 months of the incident.

3.13 Investigation:
An investigation is a detailed enquiry or systematic examination with a purpose of uncovering and clarifying issues, thereby making it easier to establish facts, context and root causes, enabling the identification of a solution.

3.14 Root Cause Analysis (RCA)
A problem solving methodology for discovering the real causes of the problems, or difficulties, identified via a range of activities including incident/event management.

3.15 Levels of investigation
The nature, severity and complexity of serious incidents vary on a case by case basis and therefore the level of response should be dependent on, and proportionate to the circumstances of each specific incident. The Chief Medical Officer / Chief Nursing Officer will use the information obtained from Datix and the Initial Case Review (ICR) to decide the level of investigation based on the NHS England SI Framework definitions of concise, comprehensive and external.

3.16 Initial Case Review
An organisational tool to record incident description and immediate actions taken to provide an initial summary of the incident and/or the formulation of a 72 hour report where necessary.

3.17 External Agency
Some classes of incidents must be reported to external agencies who may carry out their own investigation. External agencies include:

- Clinical Commissioning Groups
- Health & Safety Executive
- The Police, HM Coroner
- The Care Quality Commission
- Health Protection Agency
- NHS Improvement.

3.18 HSE
Health and Safety Executive
The HSE require certain incidents to be reported to them:

- Accidents resulting in the death of any person
- Accidents resulting in specified injuries to workers
- Accidents to non-workers (e.g. patient/ service user/visitor) at the hospital, and suffering specific injuries- see **Appendix 5 for information relating to RIDDOR reporting patient harm and Appendix 6 for a flow chart regarding RIDDOR reporting of serious patient falls.**
- non-fatal accidents requiring hospital treatment to non-workers and dangerous
- an employee suffering a specified occupational diseases or is exposed to carcinogens, mutagens and biological agents
- Specified dangerous occurrences, which may not result in a reportable injury, but have the potential to do significant harm

The Health and Safety Policy provides more information in relation to this.

3.19 Memorandum of Understanding
A protocol for liaison and effective communication between the NHS, Association of Chief Police Officers and the HSE to be followed when investigating incidents involving unexpected death or serious untoward harm.

3.20 Duty of Candour
The volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made. (Francis, 2013).

3.21 Datix
Risk Management software utilised by the Trust to record and manage all incidents and complaints.

3.22 DIF 1 (Datix Incident Form 1)
This is the electronic form on which incidents are reported.

3.23 DIF 2 (Datix Incident Form 2)
This is the electronic form on which incident investigations are recorded and to which evidence and other documents can be attached.

4. Responsibility and Duties
While this policy applies to all staff, a number of key individuals and committees have specific responsibilities under this policy and these are described below.

4.1 Key Individuals

Chief Executive

- The Chief Executive has an overall responsibility for ensuring that the Trust has systems in place to meet the "Duty of Quality", a legal requirement in the Health and Social Care (Community Health and Standards) Act 2003 and for complying with for ensuring that the Trust is compliant with the Health and Safety at Work Act 1974 and associated legislation.

Chief Nursing Officer (CNO)

- As the designated Executive lead for risk management and quality, with responsibility for the Clinical Governance and Patient Experience Departments, the CNO is responsible for the production of strategies, policies, processes, monitoring arrangements and reports related to incidents, PALS, complaints, claims, investigations and analysis of such.

- As the Director of Infection Prevention and Control (DIPC), the CNO has a specific responsibility for the systems in place for incidents related to healthcare acquired infections and attends the Trust Infection Prevention and Control Committee (TIPCC)
- He/she is a member of committees associated with investigation, analysis and implementation of learning.

Chief Medical Officer (CMO)

- The CMO is the Executive lead for patient safety and carries specific responsibilities for all matters pertaining to professional conduct of medical staff.
- He/she is a member of committees associated with the investigation, analysis and implementation of learning.

Executive Directors

- All Executive Directors will adhere to the principles underpinning this policy and take steps to ensure that their business unit complies with this policy
- When appointed to act as designated lead Executive for an investigation, to oversee the Investigation process and in the event of a serious incident report the matter to the Trust Board, NHS Improvement and Commissioners, as appropriate.
- In the case of Serious Incidents, to appoint an investigating officer, involve external agencies as appropriate, agree terms of reference, monitor ongoing investigations and take action arising out of the investigation within their area of responsibility (see Incident Reporting Policy).

Divisional Management Teams (Medicine, Operations, Nursing Directors)

- To ensure that this and related policies are effectively implemented by their Division and evidence of learning from incidents can be demonstrated.
- Assign investigation leads to serious incidents/near misses using colleagues from outside the Division when required, within 2 days of knowledge of the serious incident. (This excludes Never Events which will be investigated by the corporate teams).
- To develop suitable terms of reference for each SI investigation.
- Implement suitable Divisional governance arrangements for investigation, report writing, review and approval for presentation to the Serious Incident Review and Learning Group and ensure sign-off / response within the required timescales.
- Ensure actions resulting from investigations are SMART, and are completed satisfactorily, with evidence and are effective in resolving the cause / contributory factor identified – and take action where this has not occurred.

Divisional Clinical / Quality Governance Facilitators

- To act as link between the corporate departments and the clinical divisions/ directorates, providing support in all aspects of the investigation and analysis processes related to incidents, PALS, complaints and claims including: information gathering, timeline production, obtaining statements, arranging round table meetings and report writing; so that the investigation reports are produced within agreed timescales.
- To monitor progress with incident investigations and completion within the expected timescales, escalating delays to senior colleagues for action
- To assist their Divisions and Directorates in producing reports on incident and trend information and developing, implementing and monitoring suitable action plans.
- To provide information on relevant learning identified from within and without the Trust.
- To work with members of the Clinical Governance and Patient Experience Teams to effectively undertake their role.
- To provide training for staff within Divisions commensurate with job role.

Lead Investigators

- Must not have any Declarations of Interest in relation to the incident. If they feel that there is a Declaration of Interest, they must alert the governance team immediately so another investigator can be sought. There is an exception for falls and pressure ulcer investigations, where the ward manager is usually the Investigating Officer and may have been involved in some care. This will also be undertaken with the Matron.
- To conduct investigations and produce reports in accordance with this policy when appointed by a Divisional Director or Executive Director to do so.
- To seek and undertake adequate training to perform this role.
- To seek advice from specialist departments such as the Patient Safety Team
- To be the lead for action plans in ensuring their completion, and evidence provided on DATIX or delegating this role if appropriate.
- To ensure that staff involved in the investigation process are sited on the full report. In cases where information provided by a member of staff (e.g. from their statement) is referenced in the report, the member of staff must be shown a copy of the report before it is approved.

All Managers

- Ensure that staff are aware of local arrangements for reporting and escalating incidents both in and out of hours.
- To investigate incidents, and to take action to minimise recurrence in line with this policy.
- To ensure staff and colleagues are aware of the pertinent findings of investigations and analysis and changes in practice required.

All Staff and Staff Representatives

- To fully co-operate in an investigation ensuring there is no unreasonable delay in providing information to the investigating officer.
- Where appropriate to provide statements and attend meetings to give information. Staff are encouraged to seek assistance or advice from their Staff representative.

Clinical Risk and Governance Lead

- In conjunction with the key staff identified in this policy, to produce policies and processes that cover investigations, analysis and applying learning from incident information.
- To ensure training in investigation is available to staff and its uptake and effectiveness is monitored.
- To ensure that corporate reports required by this policy are produced to a schedule and provided to the committees and Trust staff.
- To provide outline processes to be employed in sharing learning from incidents.
- To monitor and report on the effectiveness of this policy and actions required to improve.
- To be a member of and/or report to relevant committees.

Patient Safety and Risk Manager

- Providing a strategy and assurance systems for risk management and patient safety.
- Influencing senior management to develop both a risk and safety culture within the Trust
- Providing direction and support to lead managers, Executive Directors, Divisional Directors and support staff to implement and maintain systems for risk management and patient safety and .prepare for assessments and inspections.
- Managing the teams providing corporate level support for patient safety and risk management
- Training and supporting the Trust's staff to improve their understanding of risk management and patient safety and the effective use of tools and techniques to deliver effective systems and achieve the desired outcomes

Senior Patient Safety Advisor / Patient Safety Advisor

- To monitor patient safety incidents, assist with investigations as required and to report incidents identified as Serious Incidents (SI) to commissioners.
- To provide training and support to Divisional Clinical Governance Facilitators and Investigation Leads to enable them to effectively investigate the incident/near miss.
- To monitor the Division's performance in providing SI reports within timescales and to be the primary point of contact to liaise with Commissioners and other organisations.
- To prepare a Trust-level analysis of clinical incidents for the identification of trends for reporting to committees and identifying priorities for action.
- To share relevant and appropriate learning from investigations and analysis to individuals, managers and external organisations to promote improvements.
- To lead on specific safety initiatives as identified through the investigation and analysis processes.

Health & Safety Manager & Local Security Management Specialist

- To monitor incidents related to Health & Safety and security, reporting such to the appropriate organisations.
- To undertake investigations in line with this policy or assist managerial staff in their investigation of Health & Safety and security incidents.
- To prepare analysis of incidents related to Health & Safety and security for the identification of trends for reporting to committees and identifying priorities for action.
- To share relevant and appropriate learning from investigations and analysis to individuals, managers and external organisations to promote improvements.
- To lead on specific safety initiatives as identified through the investigation and analysis processes.
- To provide training and support to staff in the investigation, analysis and implementation of actions designed to improve staff, visitor and patient safety.

Head of Legal Services

- To produce polices and processes covering claims, inquests and settlements.
- To liaise with and support lead investigators, Clinical Governance Facilitators and other corporate teams where investigations overlap with claims and inquests to ensure that suitable and accurate information is provided at the required time.
- Provide analysis to individuals, managers and external organisations to promote improvements.

Medicines Safety Officer (MSO)

- Promote the safe use of medicines across their organisations and be the main expert in this area.
- In addition to improving the quality of reporting, the MSO will serve as the essential link between the identification and implementation of (local and national) medication safety initiatives and the daily operations to improve patient safety with the use of medicines.

4.2 Committees

Quality Governance Committee (QGC)

This Committee is chaired by a Non-Executive Director and is a sub-committee of the Trust Board.

- The QGC receives reports from committees.
- The Chair will report on an exception basis any matters relating to quality governance including Never Events and serious incident as required to the Trust Board.

Clinical Governance Group (CGG)

The CGG is chaired by the CNO and in relation to this policy, meets monthly to:

- Receive a regular report on the management of SIs and outcomes / learning from investigations from the Serious Incident Group on a quarterly basis

- Receive reports from each Division that include performance and outcomes in relation to serious incidents investigations, actions and learning that can be shared with other Divisions.
- Receive analysis of clinical incidents on a quarterly basis to include trends.
- Provide quarterly reports to the Quality Governance Committee to include this information.

Serious Incident, Review and Learning Group (SIR&LG)

The Serious Incident, Review and Learning Group is a weekly meeting that is used to:

- Record the discussion regarding incidents that have been reported externally.
- Review final SI reports and actions to ensure lessons are learned and disseminated appropriately prior to the sharing of the report to external stakeholders.
- To monitor investigations and ensure they are within timescale, allowing opportunity for escalation if necessary.
- To monitor Duty of Candour and provide assurance that DoC is being met.
- The group approves (via the CMO/CNO) all SI reports

Divisional Quality Committees / Management Committees

- To review information on incidents, and identify appropriate action to be taken within the Directorate.
- To monitor investigations to ensure that they are carried out appropriately, a satisfactory report is provided and actions are identified.
- To review and agree their Division's SI investigation reports within set timescales – SI reports will be reviewed and closed by the Serious Incident Group
- To determine the information and learning from incidents that needs to be communicated to staff within the Directorate and beyond.
- To ensure that the actions required from investigations are implemented by management teams, monitored for effectiveness and remedial action is taken where they are not.
- To consider the findings of investigations and analysis when devising audit programmes and improvement programmes
- To provide reports demonstrating the Division's compliance with this policy and learning / change undertaken as a result of these processes.

Medicines Optimisation Committee

- Support the safe use of medicines in the organisation
- Improving reporting and learning of medication error incidents in the organisation;
- Analysing incident data, audit and other data to identify, prioritise and address medication risks to minimise harm to patients;
- Coordinating education and training support to improve the quality of medication error incident reports and safe medication practices;

5. The Investigation of Incidents.

5.1 Templates

All contemporaneous investigation templates and associated documents may be found on the Trust Intranet site:
http://nww.worcsacute.nhs.uk/clinical-systems/electronic-incident-reporting-system/

Once the investigation has commenced all documents must be referenced appropriately with documented version control.

5.2 Level of Investigation

It is unrealistic to suggest that all incidents should be, or need to be, investigated to the same degree or at the same level. The principles set out in this policy ensure an investigation is conducted at a level appropriate and proportionate to the incident. Whilst the principles of any investigation remain the same the level of detail will be determined by the type, severity and potential for learning.

5.2.1 Complaints linked to incidents

All complaints will be logged by the Complaints Team who will formally acknowledge the complaint in writing to the complainant within three working days of receipt.

If the Complaints Team consider that the complaint raises an incident that should have been reported in line with the Trust's Incident Reporting procedures, or if they suspect that the Duty of Candour may not have been followed when it should have been, they will liaise with the respective Clinical Governance Team to check, and highlight this with the Divisional Director of Nursing and the Investigating Officer.

5.2.2 Inquests linked to incidents

When the Coroner or family of a deceased patient raises concerns with the Coroner, these muct be subject to a level of scrutiny. Each case will be reviewed and an Initial Review must be undertaken and discussed at the SIR&LG, to determine whether a full investigation is necessary. The outcome of this decision will be fed back to the legal team by the responsible division, who will in turn inform the Coroner.

5.2.3 Incidents A decision on the level of investigation to be undertaken should be based on the initial review of the documentation against the expected standards to determine whether there were any significant acts or omissions in care or service delivery.

- **If there are <u>not</u> – a local investigation is undertaken (Level 1)**
- **If there <u>are</u> – a comprehensive investigation is undertaken (Level 2)**

Investigation Level	

Level 1
 	
Local investigation (concise)
	This type of investigation is most commonly used for incidents that resulted in **no, minor or moderate harm** to the patient – **or significant harm incidents where the initial review of documentation against guidelines/procedures shows that there were <u>no</u> deviations from practice**. They are suited to less complex incidents which can be managed by individuals or a small group at a local level
	It will normally:
	• Be conducted by staff who:
	  ○ Are local to the event
	  ○ Have knowledge of investigative procedures *(RCA trained when training programme complete)*
	• Involve completion of a summary (recorded in Datix) or **short report**(s) based on the comprehensive investigative report format;
	• Include the essentials of a thorough and credible investigation conducted in the briefest terms;
	• Involve the use of at least one RCA tool e.g. timeline, 5 why's;
	• Include recommendations or changes already made in the light of the event; and
	• Include an action plan to ensure implementation of any recommendations or changes

Level 2 **Comprehensive Investigation**	This type of investigation is normally used where the initial review of documentation against guidelines/procedures shows that there <u>were</u> deviations from practice e.g. for serious incidents (including 'Never Events) and <u>It will:</u>

	• Be **led by someone experienced and/or trained in RCA** • Require input from a multi-disciplinary team • Require input from staff not involved in the event or the specialty where the event occurred; • Be conducted to a high level of detail, including all the elements of a thorough investigation; • Include the use of appropriate analytical tools e.g. tabular timeline, 5 why's; • Involve the patient/relative/carer, including the offer of support / independent representation; and It must include: • A full report with an executive summary and appendices • Robust recommendations and time targeted action plan • Process for shared learning: locally / nationally It may require management of the media via the Trust's communications team
Level 3 **Independent Investigation**	This is commonly considered for incidents, of high public interest or those with the potential to attract considerable media attention. It is similar to level 2 but must be commissioned and conducted by those independent to the provider service and organisation involved.

5.3 Investigation timescales

The standards set for the completion of the investigation report and its review and closure by the appropriate Directorate, Divisional or Trust committee vary dependent on the seriousness of the incident and the level of investigation required. These dates **start when the incident is identified** and are set out in the table below:

	Local Level 1	**Comprehensive Level 2**	**Independent Level 3**
Investigation completed and report written	Within 35 working days	Within 35 working days	Agreed for each incident (usually 6 months from date of investigation being commissioned)
Approved and closed at Divisional / Trust level	Within 45/60 working days	Within 45 /60 working days	Agreed for each incident (usually 6 months from date of investigation being commissioned)

Divisional Governance Teams will set out the timescales for investigating officers, so that they are aware of when the completion dates are expected at each stage of the investigation (see role and responsibilities for IOs).

5.4 The Investigation process

5.4.1 Identification of serious incidents- see Appendix 2 for the process defined in the SI Framework

- **The SI Framework stipulates that serious incidents must be reported by the provider to the commissioner without delay and no later than 2 working days after the incident is identified.**
- Incidents falling into any of the serious incident categories listed below should be reported immediately to the CCG upon identification. This should be done by telephone as well as electronically:
  - Incidents which activate the NHS Trust or Commissioner Major Incident Plan:
  - Incidents which will be of significant public concern:

• Incidents which will give rise to significant media interest or will be of significance to other agencies such as the police or other external agencies:

(Out-of-hours, the local on-call management procedures must be followed).

- In the event of a serious incident, this must be escalated immediately to the responsible consultant and matron as soon as the error is recognised. For incidents occurring out of hours, this should be escalated to the on call manager and on call Matron for the Trust.
- Serious incidents or suspected serious incidents must be reported on DATIX as soon as the area becomes aware of the incident. They will usually be graded as 'severe harm' or 'death' and this will trigger an automatic email to relevant senior personnel within the Trust.
- In the event of a serious incident that is likely to lead to the death of a patient, the palliative care team must be contacted to ensure support can be provided in a timely way to the patient, family and staff.
- Any immediate actions required to ensure the safety of the patient(s), other service users and staff must be undertaken at the time of the incident.
- The divisional and corporate governance teams will review all serious incidents on a daily basis and liaise with each other to identify who will obtain the key information to determine whether an incident should be reported externally to the Commissioners.
- The designated person will obtain all relevant physical, scientific and documentary evidence, in order to identify if the incident is externally reportable in line with Appendix 1.
- Once the key facts are obtained this will be discussed with the divisional management team for agreement of externally reporting.
- It is often clear that a serious incident has occurred but where this is not the case the Corporate Patient Safety Team (or more senior if required) should engage in open and honest discussions with the commissioners (and others as required) to agree the appropriate and proportionate response. Where it is not known whether or not an incident is a serious incident, it is better to err on the side of caution and treat the incident as a serious incident until evidence is available to demonstrate otherwise. Serious incident reports can be downgraded and relevant records amended at any stage in the investigation. Any downgrading must be agreed with the commissioner on a case by case basis.
- All agreed Serious Incidents will be reported to the CNO or CMO for final executive agreement and the incident will then be reported on StEIS and internal notifications will be sent by the Patient Safety Team.
- The ICRs will be discussed at the relevant divisional governance team meeting and the terms of reference and lead investigator will be agreed. The SIL&RG will be provided with a weekly list of all incidents that have been reported as SIs.
- Falls resulting in serious harm are outlined in the flow chart in Appendix 7.

4.4.2 72 Hour Review

- When a serious incident is reported, an initial review (known as a 72 hour review) should be undertaken and uploaded onto StEIS. The 72 hours is 3 working days. Key areas where a response is required will be identified by the Clinical Commissioning Group (CCG) and will focus on areas where early assurance is needed. This is to ensure that the CCG and NHS England are kept informed regarding provider actions in managing and investigating the incident. The ICR can be used as the 72 hour report and will be sent to the commissioners by the Patient Safety Team.
- An investigation is the process of obtaining, collating and interpreting information to determine causal factors and subsequent action. The Trust uses the principles of Root Cause Analysis (RCA) to conduct its investigations.
- The Trust has an investigation toolkit to help investigators conduct a thorough and credible investigation. This is available on the Trust Intranet, under the DATIX section. Investigations must be conducted with due regard to other duties and policies of the Trust e.g. Caldicott principles on

patient confidentiality, Data Protection Act 1998 requirements, the right of employees to seek advice and help from a Trade Union, duties under investigation of fraud and the requirement of the Trust to report Serious Incidents to other bodies.

- Incident investigations will result in a written record of the findings (either as part of the incident record in Datix or as a separate report e.g. for incidents requiring an ICR or comprehensive level of investigation) and, where necessary, recommendations to improve practice. These may be recorded as action plans or a separate 'task and finish' group created to turn recommendations into an action plan and see them through to completion. This can be particularly useful for serious, complex or cross Directorate investigations.
- For incidents where staff members have been involved, the Just Culture Tool (NHSI) can be used to support staff and managers in ensuring that a fair and consistent process is used across the NHS. It is important to remember that staff may be accountable and responsible for an error but not always culpable, and the Just Culture Guide is an effective toolkit to allow managers to consider actions and alternatives to suspension. The link for the guide is: https://improvement.nhs.uk/documents/2490/NHSi_just_culture_guide_A3.pdf

5.4.3 Round Table Meetings

It is beneficial to convene a multi-professional team review. This should be regarded as a positive process providing an opportunity for the team involved in the events that subsequently led to a patient safety incident to meet, review chronology of events and causal factors and subsequently generate recommendations.

A round table meeting needs to consider which staff should be present and who will facilitate the meeting. Staff must be trained in facilitation to enable an effective meeting. The main discussion points from a round table must be documented.

Further guidance for round tables is provided in the Investigation Toolkit

5.5 Being Open/ Duty of Candour and Supporting Staff involved in Traumatic incidents – See Appendix 5

Support for patients/carers/relatives and staff is an important part of the process. Being involved in an incident, complaint or claim which is under investigation can be a very stressful experience.

- **Supporting Staff** - The responsibilities, processes and options for supporting staff through the investigation are described in the **Supporting Staff Involved in Incident, Complaints or Claims Policy** and must be applied as required.
- All staff involved in an incident must be given the opportunity to participate in an investigation and be provided with a copy of the final report.
- **Being Open / Duty of Candour** - Under the Duty of Candour it is mandatory that healthcare professionals and managers inform patients about actions which have resulted in harm. Wherever possible and appropriate, patients should be informed of an incident and should receive an apology for the harm that has resulted from the event (saying sorry is not an admission of liability and is the right thing to do).
- The responsibilities, processes and options for supporting patients, carers and relatives are set out in the **Being Open (Duty of Candour) Policy** which must be used in conjunction with this policy. The Duty of Candour requires providing an apology to patients and/or relatives following an incident and explaining what happened. It ensures communication is open, honest and occurs as soon as possible following the incident with contact maintained during the investigation and feedback of the findings. The process applies to incidents where patients suffered significant harm, not near misses.

Timing

- The initial discussion with the patient/carers/relatives should occur as soon as practical and **within 10 working days** of the incident being reported or after recognition of the incident.
- Within **10 working days** of the investigation report being signed off as complete, a copy must be supplied to the patient / relative with an offer to meet to discuss it. Providing an explanation of the findings in plain English should be considered.

In summary, the process is as follows:

- The lead Clinician will inform the patient, carer or next of kin that an incident has occurred and will apologise.
- This initial communication will be followed up with a Duty of Candour letter which will explain the process and offer the patient, carer or next of kin involvement in the investigation. A copy of the final report will also be offered.
- Details of all conversation and communications will be annotated in the patient's notes and recorded in Datix
- Copies of letters and notes of other communications will be uploaded onto the relevant Datix report.

5.6 **Approval of Investigation Reports**

Reports that have not been reported externally and being managed by the division should be approved at divisional level. Any changes sggested by the senior divisional team must be discussed and agreed by the lead investigator.
Any divisional reports that have shared Trust wide learning should be shared at the SIR&LG.
All SI reports should be reviewed and ratified by at the Divisional Governance Meetings and approved at SIR&LG.
Any changes suggested by the SIR&LG must be discussed and agreed by the lead investigator.
All staff involved in the investigation process must be sited on the full report. In cases where information provided by a member of staff (e.g. from their statement) is referenced in the report, the member of staff must be shown a copy of the report before it is approved.
A quarterly update of SI reports approved should be reported to the Clinical Governance Group.
Never Events reports should be reported to the Quality Governance Committee and Trust Board once approved

5.6.1 **Downgrading of incidents**

Where it is not clear whether or not an incident fulfils the definition of a serious incident, providers and commissioners must engage in open and honest discussions to agree the appropriate and proportionate response. It may be unclear initially whether any weaknesses in a system or process (including acts or omission in care) caused or contributed towards a serious outcome, but the simplest and most defensible position is to discuss openly, to investigate proportionally and to let the investigation decide. If a serious incident is declared but further investigation reveals that the definition of a serious incident is not fulfilled- for example there were no acts or omissions in care which caused or contributed towards the outcome the incident can be downgraded. This can be agreed at any stage of the investigation and the purpose of any downgrading is to ensure efforts are focussed on the incidents where problems are identified and learning and action are required.

5.7 **Monitoring Action Plans**

Actions must be SMART and consideration can be given to linking to incident themes.
Monitoring of progress against action plans, including the dissemination of lessons/learning, will be undertaken at Division and Directorate level at the Quality Governance / Directorate meetings and (with reference to the severity of the incident) at Directorate Performance Reviews and by the Trust's Committees.

The Investigating Officer (or delegated other) is responsible for uploading the actions onto DATIX and ensuring actions are closed within timescales, with evidence also saved in DATIX.
The SI R&L G will review the assurance of completed action plans for selected SI at intervals determined by the group.

5.8. **Learning & Feedback from Investigations**

Communication and feedback to staff involved in the incident, complaint or claim is essential for debriefing as soon as possible after the event and to learn from the findings of the investigation. This will normally be provided by local/Directorate management for the area that experienced the event or the lead investigator if appropriate.

As part of the feedback and learning process, the findings of the investigation will be made available by the investigator, senior clinical lead or the relevant manager to the following:

- Patient / relevant person (as defined in the Being Open (Duty of Candour) Policy) by the Senior Clinician responsible for care of the patient
- The clinical team(s) involved in the incident – by the relevant manager
- Other clinical teams, wards or departments performing similar activities – by the relevant manager
- The incident reporter – by the relevant manager / via automatic email from Datix when the incident is closed – or if the incident is an SI, the full report will be provided to them.
- For complaints, learning is shared through Divisional Quality Governance leads and at ward / department manager level. Trust-wide learning is shared through the Patient & Carer Experience Expert Forum.
- Other organisations that may learn from our experience – relevant manager / clinical lead

The generation of Internal Patient Safety Lessons for dissemination across the Trust is managed through the S I, R and L G and the Patient Safety Team

6. Implementation of the Key Document

6.1 Implementation arrangements

The implementation arrangements are detailed in Supporting Document 1.

6.2 Dissemination process

This policy will be made available on the Trust Intranet. A bulletin Board notice and Trust-wide e-mail will be used to announce its publication.
Copies will also be sent directly to Divisional Directors, Clinical Directors, Matrons and Directorate Managers.

6.3 Training and awareness

The training requirements are set out in a Training Needs Analysis and include the following:

- Staff appointed to lead Level 2 comprehensive investigations will be required to complete formal training in root cause analysis
- Training will be provided to other staff identified in a training needs analysis as in-house capacity is developed and implemented.
- All staff will have access to the Trust toolkit, which is based on the NPSA e-learning package for root cause analysis
- General awareness and training related to the investigation process is provided on the Trust's induction programme.

7. Monitoring and compliance

The following indicators will be used to monitor compliance with and the effectiveness of this policy:

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Also responsible for ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	Implementation of risk reduction measures: Application of the learning process – improvements from local and organisational & changes in organisational culture and practice 2.5 e) 2.6: f) g) 1.5.7	Evidence of actions implemented for: • SIs – follow-up of investigation reports to determine the effectiveness of the actions taken • Analysis / Review actions – review impact of the actions taken in response to the findings of the review and within timescale agreed	Each meeting Each meeting Twice yearly	SI Review and Learning Expert Forum Divisional Quality Governance meetings Complex complaints at the PCEEF Head of CG & RM		Quarterly Quarterly Twice yearly
	Training of staff in RCA – & Datix incident module	• Review of compliance via TNA monitoring	Annually	Training Department Head of CG & RM		Annually
	Sharing learning across the local health community 2.5 d)	Evidence of learning from incidents, complaints and claims being shared with the Health & Care Trust, Commissioners and other care providers – Committee minutes, letters,	Annually	Head of CG & RM		Annually

8. Policy Review

This policy has been developed from the SI Framework and with reference to materials provided by the NPSA and the Trust's own policies. It will be reviewed every 2 years or before should significant changes be required.

9. References

Serious Incident Framework, DH, March 2015
Revised Never Events Policy and Framework, DH, March 2015
Serious Incident (SI) Management Policy & Procedure, Worcestershire CCGs March 2016
Managing Incidents in National NHS Screening Programmes UK National Screening Committee guidelines (October 2015)
Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation (IG SIRI) May 2015
The Never Events list 2015/16, DH March 2015
Caldicott Guardian Manual 2012 www.dh.gov.uk/publications
Department of Health (2000) An organisation with a memory, Stationary Office, London. ISBN 011 322441 9.
Department of Health (2001) Building a safer NHS for patients. www.doh.gov.uk/buildsafenhs
ALARM/UCL (1999) Protocol for the analysis of clinical incidents.
7 Steps to Patient Safety – (2004) NPSA
Just Culture Guide NHSI https://improvement.nhs.uk/documents/2490/NHSi_just_culture_guide_A3.pdf
National Framework for Reporting and Learning from Serious Incidents Requiring Investigation (NPSA 2010)
National Reporting and Learning System (NRLS) NPSA
Memorandum of Understanding: Investigating Patient Safety Incidents involving unexpected death or serious untoward harm (2006)
Being Open - http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077
NHS Counter Fraud & Security Management Service
Guidance for notifying the HTA of serious untoward incidents in the post mortem sector –May 2010
CQC - Fundamental Standards of Quality and Safety as contained within the Health & Social Care Act
NHS/PSA/D/2014/005 Stage Three: Directive - Improving medication error incident reporting and learning 2014

Related Trust Documents.

Risk Management Strategy
Security Policy (WAHT-CG-034)
Being Open (Duty of candour)
Concerns & Complaints Policy and Procedure
Supporting Staff involved in Traumatic / Stressful Incidents, Complaints & Claims (WAHT-HR-002)
Health and Safety Policy
COSHH Policy
Medical Devices Policy
Obstetric Risk Management Strategy
Risk Register (Datix)
Public Interest Disclosure (Whistle blowing) Policy
Disciplinary Policy
SUDIC –Investigations of sudden & unexpected deaths in children under 18 years
Infection Control Manual Inoculation Injury Protocol

10. Background

10.1 Equality Requirements
An equality assessment has been performed. There are no equality issues presented by this policy.
Supporting Document 1

10.2 Financial risk assessment
A financial risk assessment has been performed. While there are no direct financial implications associated with this policy, effecting change as a result of learning may have associated costs. These will be dealt with through individual business cases supported by risk assessments `
Supporting Document 2

10.3 Consultation Process
The following were consulted in the production of this policy:

- Executive Directors
- Members of the SIR&LG and Medicines Safety Committee
- Divisional management teams
- Clinical Directors
- Directorate Managers
- Matrons
- JNCC

10.4 Approval process
This policy will be approved by the Clinical Governance Group following consultation as described above

Appendix 1

Identification of a Serious Incident (taken from the SI Framework, 2015)

In broad terms, 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 organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

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

There is no definitive list of events/incidents that constitute a serious incident and lists should not be created locally as this can lead to inconsistent or inappropriate management of incidents. Where lists are created there is a tendency to not appropriately investigate things that are not on the list even when they should be investigated, and equally a tendency to undertake full investigations of incidents where that may not be warranted simply because they seem to fit a description of an incident on a list. The definition 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 description below. Inevitably, there will be borderline cases that rely on the judgement of the people involved.

Serious Incidents in the NHS include:

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

- Unexpected or avoidable death of one or more people. This includes
    - suicide/self-inflicted death; and
    - homicide by a person in receipt of mental health care within the recent past
- Unexpected or avoidable injury to one or more people that has resulted in serious harm;
- Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent
    - the death of the service user; or
    - serious harm;
- Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
    - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
    - where abuse occurred during the provision of NHS-funded care.
    - This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident

- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See Never Events Policy and Framework for the national definition and further information.
- An incident that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
    - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues (see Appendix 2 for further information);
    - Property damage;
    - Security breach/concern;
    - Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
    - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
    - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services)
    - Activation of Major Incident Plan (by provider, commissioner or relevant agency)

- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

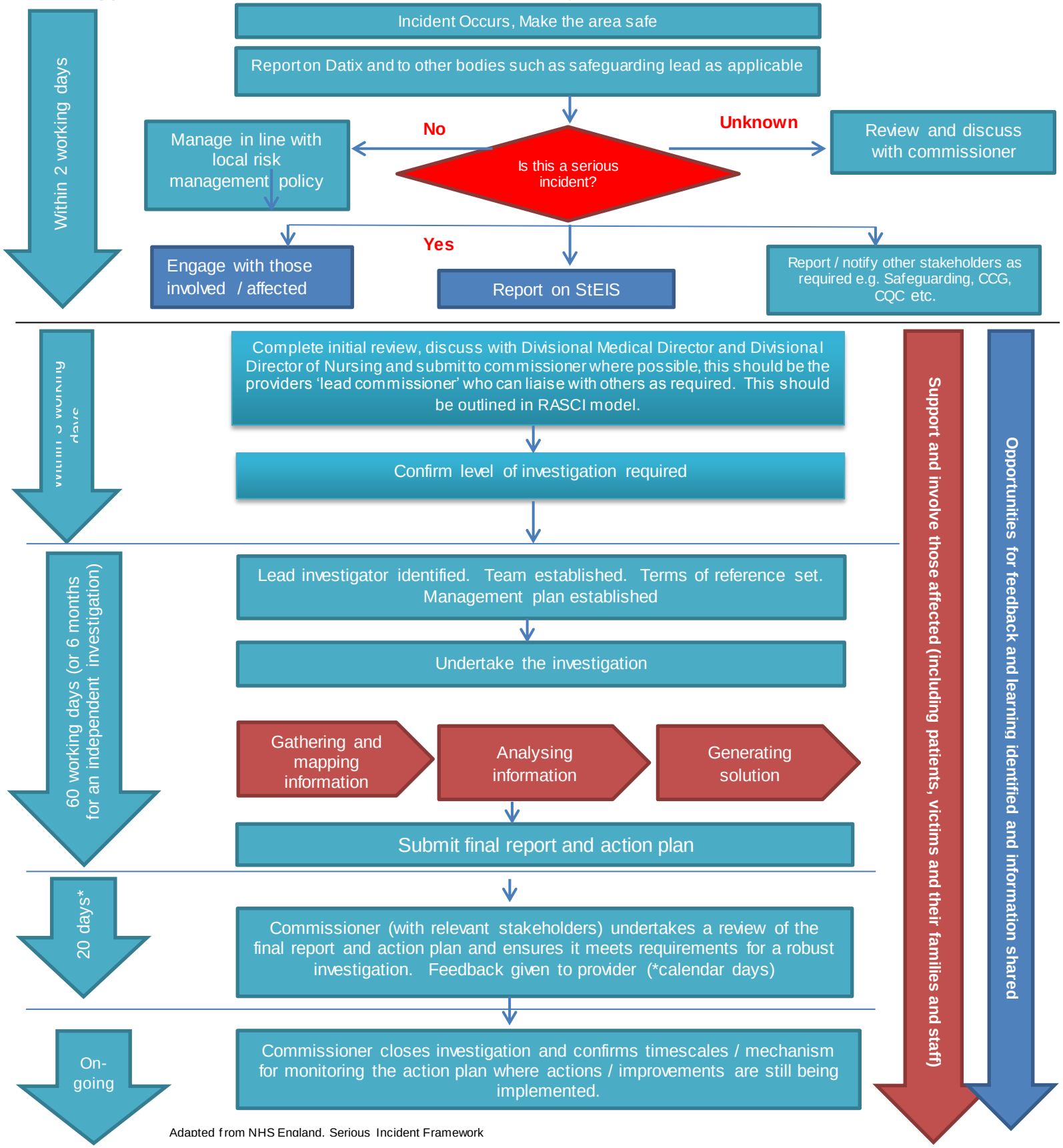
Assessing whether an incident is a serious incident

In many cases it will be immediately clear that a serious incident has occurred and further investigation will be required to discover what exactly went wrong, how it went wrong (from a human factors and systems-based approach) and what may be done to address the weakness to prevent the incident from happening again.

Whilst a serious outcome (such as the death of a patient who was not expected to die or where someone requires on going/long term treatment due to unforeseen and unexpected consequences of health intervention) can provide a trigger for identifying serious incidents, outcome alone is not always enough to delineate what counts as a serious incident. The NHS strives to achieve the very best outcomes but this may not always be achievable. Upsetting outcomes are not always the result of error/ acts and/ or omissions in care. Equally some incidents, such as those which require activation of a major incident plan for example, may not reveal omissions in care or service delivery and may not have been preventable in the given circumstances. However, this should be established through thorough investigation and action to mitigate future risks should be determined.

Where it is not clear whether or not an incident fulfils the definition of a serious incident, providers and commissioners must engage in open and honest discussions to agree the appropriate and proportionate response. It may be unclear initially whether any weaknesses in a system or process (including acts or omissions in care) caused or contributed towards a serious outcome, but the simplest and most defensible position is to discuss openly, to investigate proportionately and to let the investigation decide. If a serious incident is declared but further investigation reveals that the definition of a serious incident is not fulfilled -for example there were no acts or omissions in care which caused or contributed towards the outcome - the incident can be downgraded. This can be agreed at any stage of the investigation and the purpose of any downgrading is to ensure efforts are focused on the incidents where problems are identified and learning and action are required.

Appendix 2: Overview of the Serious Incident Management Process from the SI Framework



Adapted from NHS England, Serious Incident Framework

Appendix 3 – Duty of Candour

The National Learning & Reporting System (NLRS) definitions of harm & timescale guide.

The **Duty of Candour** applies to any incident causing **SIGNIFICANT HARM** i.e. **Moderate, Severe or Death**.			**Duty of Candour applies?**
No harm		• **Incident prevented / near miss.** • **Incident not prevented but no harm was caused**	**No**
Minor Harm		**Any patient safety incident that required extra observation or minor treatment and cased minimal harm to one or more patients** • e.g. first aid, additional therapy or additional medication **It is not minor harm if the incident results in:** • any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned; • or an unplanned return to surgery or readmission.	**No**, but provide a verbal apology
Significant Harm	**Moderate Harm**	**Any patient safety incident that resulted in a moderate increase in treatment and that caused significant but not permanent harm to one or more patients** Moderate increase in treatment is defined as: • 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 area such as intensive care **as a result of the incident.**	**YES** **Duty of Candour applies** **Implement Being Open process**
	Severe Harm	**Any patient safety incident that appears to have resulted in permanent harm to one or more patients** Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as: • permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage.	
	Death	Any patient safety incident that directly resulted in the death of one or more patients • The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.	

Being Open Process – Significant Harm

STAGE 1	**Incident detection or recognition** 1. The first priority is prompt and appropriate clinical care and the prevention of further harm 2. Complete an incident form in Datix
STAGE 2	**Preliminary Team Discussion:** 1. Appoint a member of staff (experienced and with expertise) to lead on communication with the patient or service user/carer – usually the most senior clinician with responsibility for the patient's care 2. Establish which other staff members should attend. 3. Establish a time line. 4. Establish the aims of the meeting. 5. Offer support and counselling for staff involved if required.
STAGE 3	**The Initial Discussion** <u>Within 10 working days of the incident</u>: 1. Establish how to contact patient or service user/carer. 2. Verbally inform the patient, provide an apology and follow-up in writing 3. Agree venue and time for a meeting with patient or service user/carer. Meeting: 4. Introduce everyone in the meeting, including what their roles are. 5. Provide factual details to date. 6. Offer practical and emotional support. 7. Provide contact details of who to contact if patient or service user/carer have further questions. 8. Identify and agree next steps.
STAGE 4	**Follow-up Discussions** 1. Keep patient or service user/carer informed of how the investigation is going 2. Consider keeping in touch on a regular basis with the service user/carer. 3. Respond to any queries as sufficiently as possible
STAGE 5	**Completing the Process** 1. <u>Within 10 working days</u> of the investigation being signed off as complete, a copy must be supplied to the patient / relative with an offer to meet to discuss it. 2. Consider the best way to provide the findings of the investigation to the patient 3. Provide: a repeated apology; a chronology of facts and findings of the investigation; a summary of contributing factors; what is, or will be done to avoid a recurrence 4. Arrangements for continuity of care where required should be agreed 5. Share the key findings / summary with all staff concerned 6. Make arrangements to monitor the plans 7. Share the learning with staff in the Trust

All discussion with the services user, their family and carers should be documented at all times by the key contact / senior clinician

Note: Any incident defined as a **NEVER EVENT** will have the Being open policy applied irrespective of the level of harm caused to the patient.

Appendix 4:

Serious Incidents involving patient harm.

Is the incident RIDDOR reportable?

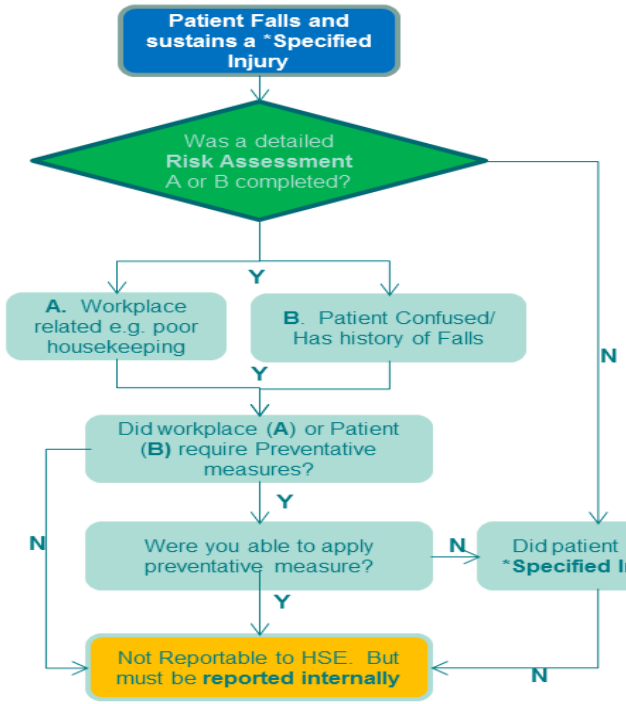
The following questions are used to determine whether or not the incident is reportable to the HSE. Please complete and return the form ASAP to the H&S Manager:

Incident Number: **WEB……** RIDDOR Reportable: **YES/NO**

Question:	Yes:	No:	N/A:	Any comments:
1. Was there a fault with any item of equipment involved in this accident?				
2. If a fault was identified was it a contributory factor?				
3. Did the patient present with a history of falls?				
4. Had a Falls Assessment been carried and if so on what date?				Date completed:
5. Did a Falls Assessment identify the need for any falls protection e.g. cot-sides, additional staffing levels for 1 to 1 care etc.?				Give details of level of protection:
6. If so, were these protection measures suitably implemented?				
7. If the patient had been assessed as susceptible to falls and had been left alone for example for dignity reasons was there a member of staff within earshot to respond to a shout or a call bell if the patient required assistance?				
8. If as above the patient had been left alone did they then choose to mobilise themselves without asking for assistance?				
9. Were there any environmental hazards identified as being a contributory factor in this accident for example wet floors, trailing leads, power failure etc.?				Give details of hazard:
10. If a slip, trip or fall hazard was identified was there an appropriate hazard warning sign on display at the time of the accident?				

If in doubt please contact the Health & Safety Manager on Mobile 07887982803 for advice.

Appendix 5



RIDDOR

Patient Falls Incident Reporting: Internally and to the Health and Safety Executive (HSE)

- **Specified Injuries** are defined in the RIDDOR Regulations. It includes Fractures (not fingers, thumbs or toes), Burns, including scalding, and loss of consciousness due to a head injury
- ****RIDDOR** = Reporting of Injuries, Diseases, and Dangerous Occurrences Regulations 2013

Example 1 Not Reportable to HSE but MUST be reported Internally	Example 2 Reportable to HSE as a RIDDOR
• If the patient is found on the floor, no-one saw it happen, there were no obvious contributing factors and the risk assessment/care plan identified fall protection was not required. • A patient falls out of bed and requires treatment. There was a detailed assessment in the Care plan that identified fall protection was not required.	• They fall and there is previous history of fall incidents, but reasonably practicable measures to reduce the risks have not been put in place. • They fall out of bed and the assessment had identified the need for bedrails but they, or other preventative measures, had not been provided. • They trip over mats, wires, boxes etc. and sustained a specified injury • A confused patient falls from a hospital window on an upper floor and is badly injured.

Appendix 6: Falls Incident Reporting Process

Patient fall reported on Datix within 1 day.

Datix monitored by Ward/Department Manager, Safer Care Practitioner- Falls and Divisional Governance Team.

No harm/minor harm falls to be reviewed, investigated and closed by the Ward/Department Manager within 20 days on Datix.

Moderate harm/severe harm/death falls to be reviewed by Ward/Department Manager and/or Matron and discussed with Safer Care Practitioner- Falls and/or Divisional Governance Team to establish **level of investigation required*** within 2 working days**.** Patient Safety Team to be informed of any externally reportable falls to report on StEIS.

***Level of investigation required**
The same report template will be used however the level of investigation depends on whether this is reported externally (#NOF/HI) or investigated internally (falls with less significant harm).

ICR checklist/RIDDOR questionnaire completed within 3 working days and sent to Safer Care Practitioner-Falls and Divisional Governance Team (available on DATIX home page on intranet).
Save ICR checklist/RIDDOR questionnaire to Datix.
If not completed within time frame escalate to DDN.

Omissions in care identified

YES- Divisional Governance Team to allocate an RCA trained Investigating Officer (IO) and Matron of IO to arrange a falls debrief meeting with Safer Care Practitioner- Falls and Divisional Governance Team for the following Tuesday (AGH) or Thursday (WRH).
Save debrief minutes to Datix.

NO- ICR checklist/RIDDOR to be presented to the Divisional Governance Meeting for agreement to downgrade

Investigating Officer (IO) to complete RCA and present to the Divisional Governance Meeting within 25 days for sign off
RCA to be sent to Safer Care Practitioner- Falls within 1 week of being presented for review, feedback and changes

Signed report to be submitted to the Serious Incident and Learning Group (SIRLG) within 40 days for sign off

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the Policy/guidance affect one group less or more favourably than another on the basis of:**		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Disability	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
2.	**Is there any evidence that some groups are affected differently?**	Yes	Recognition that some groups are less likely to complain than others such as older people and those with Learning Disabilities. We are adding statements to our literature and website to positively support people to provide feedback to help us improve services.
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	No	As above we have recognised the potential for discrimination and are putting in place actions to try and mitigate these.
4.	**Is the impact of the Policy/guidance likely to be negative?**	No	
5.	**If so can the impact be avoided?**	n/a	
6.	**What alternatives are there to achieving the Policy/guidance without the impact?**	n/a	
7.	**Can we reduce the impact by taking different action?**	n/a	

If you have identified a potential discriminatory impact of this key document, please refer it to Assistant Manager of Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Assistant Manager of Human Resources.

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	Yes Additional costs have been funded through the training budget
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval