POLICY DOCUMENT

Burton Hospitals
NHS Foundation Trusts

INCIDENT AND SERIOUS INCIDENT MANAGEMENT POLICY AND PROCESS

Approved by:	**Trust Executive Committee**
On:	**30 May 2017**
Review Date:	**April 2020**
Corporate / Directorate	**Corporate**
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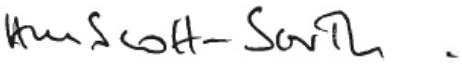
Signature:	
	Chief Executive
Date:	**30 May 2017**

Burton Hospitals NHS Foundation Trust

POLICY INDEX SHEET

Title:	**Incident and Serious Incident Management Policy and Process**
Original Issue Date:	**July 2014**
Date of Last Review:	**April 2017**
Responsibility:	**Chief Nurse**
Stored:	**Policy Section Intranet Site**
Linked Trust Policies:	• Whistleblowers Policy • Risk Management Strategy • Risk Management Policy and Procedure • Complaints Policy and Procedure • Policy for the Handling of Clinical Negligence and Personal Injuries and Claims Handling Procedure • Policy and Procedure for the Management of Health & Safety • Anti-Fraud and Bribery Policy • Major Incident Plan • Management of Violence and Aggression • Withholding of treatment from patients and exclusion of relatives or visitors who are violent or aggressive • Policy for Being Open • Supporting Staff Policy • Safeguarding Adults Policy • Safeguarding Children Policy and associated procedures • Conflict Resolution Policy • Information Governance Policy
E & D Impact Assessed	**EIA 340**
Responsible Committee / Group	Serious Incident Review Group
Consulted	Executive Directors, Divisional Medical Directors, Divisional Directors, Department Heads, , Members of Quality Committee (Board sub-committee)

REVIEW AND AMENDMENT LOG

Version	Type of change	Date	Description of Change
1	New Policy - draft	March 2014	This policy replaces the Trust's Incident and Serious Incident policies. Extensive review of both policies and the inclusion of updated policy and process details.
1	New Policy - draft	3 April 2014	New integrated policy replaces the previous serious incident and incident reporting policies. Revisions take account of the *NHS England Framework for Serious Incidents Requiring investigations* (March 2013); *Guidance on the reporting and monitoring arrangements and post infection review process for MRSA bloodstream infections from April 2013* (06 March 2013); *Checklist for Reporting, Managing and Investigating Information Governance Serious Untoward Incidents – Gateway ref: 13177* (January 2013); and *HTA Reportable Incident (HTARI) reporting* -updated March 2013.
1	Inclusion of appendices	3 April 2014	Reporting templates, flowcharts, process maps and guidance**.**
1	Amendment to appendices	7 April 4014	Updated versions of safeguarding flowcharts.
1	Amendment of duties following consultation	8 April 2014	Amendment to titles, roles and committees/groups
1	Further updates following CMB members' additional comments as part of consultation May 2014	7 June 2014	Amendment to opening statement and various alterations throughout the policy
1	Further changes following consultation	11 June 2014	Various minor alterations.
1	Final draft following proof read	18 June 2014	
2	Amendment in line with Duty of Candour	9 January 2015	Amendment in line with Duty of Candour
2	Amendments made in line with NHS England SI Framework publication and Never Events list	19 May 2015	Changes made in line with NHS England SI Framework publication and Never Events list
4	Appendices updated and process	10th April 2017	Amendments made in line of new SI and ISA process and timescales

INCIDENT AND SERIOUS INCIDENT MANAGEMENT POLICY AND PROCESS

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APPENDICES

BURTON HOSPITALS NHS FOUNDATION TRUST

INCIDENT AND SERIOUS INCIDENT MANAGEMENT POLICY

1.0 OPENING STATEMENT AND INTRODUCTION

Professor Don Berwick, MD following a review of patient safety in England in response to the Francis Inquiry report February 2013 (*A Promise to Learn: A Commitment to Act* - 13 August 2013) made a set of recommendations, some of which have particular relevance to this policy:

- *Recommendation 1: The NHS should continually and forever reduce patient harm by embracing wholeheartedly* ***an ethic of learning.***
- *Recommendation 2: All leaders should place* ***quality of care*** *and* ***patient safety*** *at the top of their priorities for* ***investment, inquiry, improvement, regular reporting encouragement and support****.*
- *Recommendation 7:* ***Transparency*** *should be complete, timely and* ***unequivocal****.*

In its response to Professor Berwick's report, the King's Fund added:
We also need to prove ongoing support and model learning and openness from board to ward. Staff throughout the health service should be supported to do the right thing, be honest when they make mistakes, which they sometimes will, and speak out where they are concerned about quality of patient care.'

It is with these principles in mind that the Board of Directors (BoD) at Burton Hospitals Foundation Trust (BHFT) supports the decision to revisit and challenge the way in which it ensures that systems and processes throughout the Trust enable a positive reporting culture throughout the organisation so that we can maximise our learning when things go wrong.

We know from the considerable body of research into patient safety that fear of blame may deter staff from reporting an incident or near miss event. The Trust's Board of Directors therefore supports the view that the response to incidents should not be one of blame and retribution but of organisational learning to encourage the participation in the process and support staff, rather than to expose them to recrimination.

In particular the Board commits to the following enablers:

- Ensure that an 'open and just' culture is promoted to assure staff that the Trust operates an open and honest environment where no one will be unfairly blamed when things go wrong.
- Ensure effective record keeping and reporting mechanisms are in place.
- Ensure that all incidents are managed in a timely and organised manner.
- Ensure clear lines of accountability and responsibility are identified for all elements of incident management, including serious incidents.
- Ensure that all staff, including bank, locum and agency staff, are aware of the communication systems in place for the management of all types of incidents, via appropriate induction and training.
- Ensure key communication mechanisms are established with family and/or carers in line with the Trust's *Being Open* policy.
- Ensure all appropriate levels of debrief and communication of lessons learned takes place following incidents.

- Ensure all relevant internal and external stakeholders, agencies and regulatory bodies are engaged, involved and informed in line with national legislation and guidelines.
- Ensure lessons are learned from reported incidents, and appropriate action is taken to avoid recurrence, including making changes to practice, systems and process, and/or the environment to improve patient, staff and public safety.
- Ensure no disciplinary action will result from reporting an incident (including mistakes and near misses) **unless** there is evidence of:
    - Criminal or malicious activity
    - Professional malpractice
    - Acts of gross misconduct
    - Repeated mistakes

Under these circumstances, disciplinary action will be considered under the relevant HR policy.

Whilst wishing to support and enable a culture of openness in the interests of promotion a culture of safety and openness, the Trust has certain legal and contractual commitments it must adhere to. To meet these commitments it is important to reinforce that failure to report errors or violations is a breach of Trust policy and may be considered as part of the disciplinary process.

2.0 INTRODUCTION

The collation and analysis of data from incidents and near misses is an intrinsic part of risk management as it provides valuable opportunities to learn and improve. This policy describes the Trust's arrangements for reporting incidents of all types and levels of significance, and the actions expected to manage and follow-up such incidents to minimise the risk of them happening again. The policy supports the Trust's Risk Management Strategy and Policy and must be considered in conjunction with other Trust policies as set out at the beginning of this policy as well as legislation and national guidance described in Section 17.

Serious incidents requiring investigation (SIs) in healthcare are rare, but when they do occur, all healthcare provider organisations must make sure there are systematic measures in place to respond to them. Such measures are in order to protect patients and ensure that robust investigations are carried out, which result in learning to minimise the risk of recurrence.

All providers of health and social care in England have a statutory duty to report SIs to the body that commissioned the service where the incident occurred. Clinical Commissioning Groups (CCGs) and NHS England (as direct commissioners e.g. specialist services) are responsible for holding providers to account for managing responses to serious incidents. In addition, providers have a responsibility to report certain adverse events to the appropriate regulatory body. This includes the Care Quality Commission (CQC) and the Health and Safety Executive. As a foundation trust, BHFT has an additional responsibility to report to NHS Improvement. Section 5 sets out the Trust's duties in more detail.

3.0 PURPOSE AND SCOPE

3.1 Purpose

The purpose of this policy is to provide a means of identifying and reducing the risks to which the organisation, its patients and staff, contractors, volunteers and members

of the public may be exposed, and maintain the reputation of the Trust. The procedure (section 6 onwards) together with process maps included as appendices provide staff with clear guidance on how to respond to, report, manage and investigate incidents, including Internal Safety Alert (ISA) and serious incidents requiring investigation (SIs).

3.2 Scope

This policy and procedure applies to all staff at BHFT, whilst acknowledging that for staff other than those directly employed by the Trust, the appropriate line management will be taken into account. The document outlines how the Trust will report, manage, analyse and learn from incidents including serious incidents. Implementation however does not replace the personal responsibilities of staff with regard to issues of professional accountability.

This policy applies to all BHFT staff, including those employed on a bank, agency or locum basis including NHS professionals.

4. DEFINITIONS AND REPORTING CRITERIA

4.1 Definitions

This section describes the meaning of the **key terms** used within the context of this document. The terms listed in this section however are not exhaustive and reference should be made to the full glossary to be found at Section 16 of this document.

Incident

An event or circumstance that could have resulted, or did result, in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, contractor, volunteers, visitors or members of the public.

Near miss

Any incident that did not result in injury/ill health or property damage/loss, but that had the potential to do so.

Internal Safety Alert (ISA) **–** An incident which may or may not meet the published level one serious incident criteria but gives cause for concern. Equally, a series of incidents, irrespective of the level of harm, that suggest an emerging trend. In such cases, it is proportionate to use a concise RCA to ensure there are no unique factors that require further in-depth investigation. Resources should be focused on implementing improvement rather than conducting comprehensive investigations that will not produce new learning.

Serious Incident (SI)

A serious incident requiring investigation is defined as an incident that occurred in relation to NHS funded services and care: -

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

- 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.
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
- Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues
    - Property damage;
    - Security breach/concern;
    - Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
    - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
    - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or
    - Activation of Major Incident Plan
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation

One of the twenty five core set of ***Never Events*** as set out in the Department of Health annual published guidance (https://www.gov.uk/government/publications/healthcare-never-events-policy-framework-update).

Never events

Never events are serious, largely preventable patient safety incidents that should not occur if the available preventive measures have been implemented. The list is reviewed on an annual basis and currently include for 2015-2016:

1) Wrong site surgery
2) Wrong implant/prosthesis
3) Retained foreign object post-procedure
4) Medication
    a. Mis – selection of a strong potassium containing solution
    b. Wrong route administration of medication
    c. Overdose of Insulin due to abbreviations or incorrect device
    d. Overdose of methotrexate for non-cancer treatment
    e. Mis – selection of high strength midazolam during conscious sedation

5) Mental Health - Failure to install functional collapsible shower or curtain rails
6) Falls from poorly restricted windows
7) Chest or neck entrapment in bedrails
8) Transfusion or transplantation of ABO-incompatible blood components or organs
9) Misplaced naso- or oro-gastric tubes
10) Scalding of patients

The full definition for each never event is available on the Department of Health website: http://www.england.nhs.uk/wp-content/uploads/2015/03/never-evnts-list-15-16.pdf

Security incident
The following security incidents must be reported to the NHS Security Management Service using the *Security Incident Reporting System (SIRS):*

- Any security incident involving physical assault of NHS staff;
- Non-physical assault of NHS staff (including verbal abuse, attempted assaults and harassment);
- Theft or criminal damage (including burglary, arson, and vandalism) to NHS property or equipment (including equipment issued to staff);
- Theft of or criminal damage to staff or patient personal property;
- Properly damage arising from these types of security incident.

Major incident (to invoke Major Incident Plan)
An unexpected event that overwhelms normal resources, and that requires special measures. It would be expected to involve a large number of casualties of a variety of severity arriving in a short period of time. Following declaration of a major incident, the Trust's Major Incident Plan is invoked. A serious incident may also require the Major Incident Plan to be invoked. This decision will be made between the Chief Executive or their nominated Deputy in discussion with relevant senior clinicians. Please refer to the Trust's Major Incident Policy for further information.

RIDDOR - the Reporting of Injuries Diseases and Dangerous Occurrences Regulations 1995 (HSE 1999)
RIDDOR defines the type of incidents, diseases and occurrences that must be reported to the Health and Safety Executive to comply with statutory requirements. The full definition for each category of RIDDOR reportable incident is available at the HSE website: http://www.hse.gov.uk/riddor/report.htm

4.2 Suicides

The Trust does not provide acute adult psychiatric services, however this does not preclude the possibility of a BHFT patient suicide or attempted suicide occurring.

Suspected suicide, actual suicide and attempted suicide of any person currently in receipt of NHS services on or off NHS premises must be reported as an SI.

Suicide is defined as death where:

- There is obvious evidence or strong suspicion of self-harm, or
- The above does not apply initially but emerges later from a clinical review or investigation of the case, or
- Where the Coroner's verdict is suicide, or where the narrative indicates that the individual took their own life

Consideration of the circumstances should be made and communicated to the relevant psychiatric service provider who may be part of the coordination of the serious incident.

4.3 Safeguarding Children and Adult at Risk

Incidents reported as serious incidents when child or Adult at risk issues are identified at any stage must be referred to the appropriate Trust lead officer who will ensure the appropriate procedure is followed. All serious incidents involving safeguarding issues will be investigated in accordance with the Trust's policies for safeguarding children and Adults at Risk. See appendices 4 & 5

4.4 Healthcare Associated Infections

Any healthcare associated infection (including, but not limited to, MRSA bacteraemia, MSSA bacteraemia, *E. coli* bacteraemia, GRE bacteraemia and *Clostridium difficile* infection) that has significantly contributed to death or serious harm and/or is recorded in part one of the death certification should be reported and investigated as a serious incident.

Outbreaks of *Clostridium difficile* infection (defined as two or more cases) caused by the same strain, related in time and place, within a 28-day period, should be reported and investigated as a serious incident.

MRSA

All identified cases of MRSA bacteraemia need to be reported as an SI.

Clostridium difficile

Cases need reporting as an SI when:

- Classified as 1a and 1b on the death certificate where it is clear Clostridium difficile has made a significant contribution to cause of death.
- Cases where a serious complication including colectomy arise due to Clostridium difficile

Norovirus

Either of the following two triggers will result in the organisation reporting an SI:

1. One or more wards, including bays, closed due to Norovirus
2. An outbreak meeting has been called.

4.5 Pressure Ulcers

The European Pressure Ulcer Advisory Panel (EPUAP) defines a pressure ulcer as localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear (NPUAP-EPUAP, 2009):

http://www.epuap.org/guidelines/Final_Quick_Prevention.pdf

Pressure ulcers are categorised from 1 - 4 category definitions can be seen in the EPUAP guidelines.

- Grade 2 pressure ulcers are reported onto the Trust's Ulysses/Datix risk management system
- Grade 3 & 4 pressure ulcers are also investigated initially as a Internal Safety Alert (ISA) and escalated as a SI and reported onto STEIS if meets the SI NHS England Definition

The root cause of pressure ulcers is determined through root cause analysis to identify learning that can be used to prevent future pressure ulcers, and to determine if they are avoidable or unavoidable. The DH (undated) defined an 'avoidable' pressure ulcer as one that occurs when risk assessments, preventive actions and continued re-evaluations have not been implemented.

Inpatients at the end of life (EOL), who suddenly become critically unwell and develop unstageable pressure ulcers which breakdown within 72 hours of death can

be classified as Skin changes at life's end (SCALE). These incidents are still reported as SI's but only a SCALE statement written by a Tissue Viability Nurse needs to be submitted to commissioners to confirm that all appropriate interventions have been in place.

4.6 Maternity Services

Serious incidents in maternity services will be reported and investigated in line with this policy. The following national maternity and new born categories need to be reported as SIs:

- Maternal death - specifically those that occur whilst under booked care
- Intra uterine deaths - those over 37 weeks gestation
- Intra partum death - specifically those that die during labour or during an inpatient admission
- Unexpected neonatal death- specifically from 37 weeks gestation to 28 days post delivery
  - Maternal unplanned admission to ITU:
  - Patients requiring advanced respiratory support alone or
  - basic respiratory support together with support of at least two other organs
  - Includes complex patients requiring support for multi-organ failure
- Unexpected admission to NICU (neonatal intensive care unit)-specifically those with Apgar Score below 4 at five minutes

There is an additional requirement to report all such incidents to the Chief Nurse who is the executive lead for maternity services and Local Supervising Authority (LSA) as described in the Maternity Risk Management Strategy.

4.7 Coronial process

Her Majesty's Coroner is notified of all deaths. When a death is unexpected, violent or unnatural, the Coroner will decide whether to hold a post-mortem and, if necessary, an inquest. When a person dies in the custody of the legal authorities, including detention under the Mental Health Act, and those patients who have a deprivation of liberty authorization in place, an inquest must be held. The Coroner's court is a court of law, and accordingly the Coroner may summon witnesses to attend and give evidence. It is a legal requirement to attend, and failure to do so may result in a charge of contempt of court.

The Coroner may raise a Prevention of Future Death Report (previously known as Rule 43) following an inquest and it may be at this stage that a serious incident is raised. If the Coroner issues a 'Prevention of Future Death Report' letter, and the death was not previously investigated as a serious incident, then this must be escalated and the SI process followed.

4.8 Incidents involving national screening programmes

Where an incident involves any National Screening Programme, the appropriate Quality Assurance Reference Centre must be informed by the Trust's hospital based programme coordinator (Head BMS Pathology). The hospital based programme coordinator will be part of the investigation team and will work closely with its commissioner and be advised by the regional QA Director/Lead.

Further guidance can be obtained from *'Managing Incidents in National NHS Screening Programmes*' (UK National Screening Committee, 2013)

Managing_Incidents_in_NHS_Screening_Programmes_Sep_2013[1].pdf

4.9 Incidents involving information security

The Department of Health (DH) definition of an information governance (IG) serious incident is: *Any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious.* This definition applies irrespective of the media involved and includes both loss of electronic media and paper records. All information governance incidents must be referred to the Head of Information Governance who will ensure the incident is managed in line with the Trust's Information Governance policy; DH Information Governance Policy; and the Information Commissioner's reporting requirements.

The Trust will need to follow the latest Department of Health Guidance - Checklist Guidance for Reporting, Managing and investigating Information Governance Serious Incidents (DH, June 2013):

https://www.igt.hscic.gov.uk/KnowledgeBaseNew/HSCIC%20IG%20SIRI%20%20Checklist%20Guidance%20V2%200%201st%20June%202013.pdf

4.10 Incidents involving mortuary services related to Human Tissue Authority (HTA) Post Mortem Sector Licence

HTA-licensed establishments in the post mortem sector are required to notify the HTA of any reportable incidents (HTA Reportable Incident – HTARI), including near misses, **within five working** days of the incident being discovered. Establishments must not wait until any internal review or investigation is complete before reporting the incident. To meet this deadline, any potentially serious incident involving mortuary services or any other potential breach of the Human Tissue Act must be reported using the Trust's SI process (Appendix 2) in the normal way for executive approval to allow the Designated Individual (DI) to inform the HTA in accordance with HTA current guidelines It should be noted that the HTA SI classifications differ from the NPSA published criteria and therefore HTA current guidance should be referred to when deciding on the incident grade, and whether it meets the HTA and NPSA thresholds.

It is the responsibility of the Trust's Designated Individual (DI) to ensure HTARIs are reported to the HTA via the web portal. This is a change from the previous email notification system in place until March 2013. Only DIs and Persons Designated (PDs) are able to submit notifications using the web portal.
http://www.hta.gov.uk/licensingandinspections/reportingtothehta/seriousuntowardincidentreporting.cfm

The DI must ensure a follow-up report is submitted to the HTA via the web portal within 90 days of making the initial notification. This should ideally be a copy of the Trust's internal investigation report.

4.11 Other agencies with a remit for serious incidents

Other external organisations must be notified about incidents relevant to their statutory remit and current guidelines, such as:

- Care Quality Commission (Statutory Notifications for NHS registered providers) as the body with whom healthcare providers in England must be registered
- NHS Improvement as the licensing body for NHS foundation trusts
- Care Quality Commission on behalf of the Department of Health for Ionising Radiation (Medical Exposure) Regulations (IRMER) incidents
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Health and Safety Executive (HSE)
- NHS England

- Public Health England
- Serious Hazards of Transfusion (SHOT)
- National Screening programmes, Human Tissue Authority (HTA)
- Other breaches of the Human Tissue Act, Human Tissue Authority (HTA)

5. DUTIES

5.1 Board of Directors

The principal accountability of all providers of NHS-funded care is to patients and their families/carers. In their fulfilment of the Trust's duty in this regard, the Board must ensure that an appropriate incident management system is in place for the reporting of incidents and monitoring of incident trends, including serious incidents, and the recording of all Never Events in the annual reporting arrangements. Provider organisations are also accountable for effective governance and learning following a serious incident, and it is the duty of the Board to ensure appropriate arrangements are in place throughout the Trust to meet this expectation.

5.2 Chief Executive

The Chief Executive is accountable and responsible to the Board for ensuring that resources, policies and procedures are in place to ensure the effective reporting, recording, investigation and treatment of incidents. In practice the Chief Executive may delegate the day-to-day responsibility for this to another Executive Director together with Heads of Division or Department.

5.3 Chief Nurse

The Chief Nurse is the nominated Director responsible for ensuring that the Trust has appropriate arrangements in place for the management of incident reporting and associated investigation.

The Chief Nurse is responsible for ensuring the following systems are in place and operate effectively:

- Maintaining records of reported incidents using the Datix incident management system.
- Monitoring the appropriate reporting and grading of reported incidents, and seeking clarification from relevant managers should grading be inconsistent with trends.
- Ensuring appropriate notification of incidents to relevant internal and external stakeholders, agencies and regulatory bodies.
- Notifying the Chief Executive, Executive Directors, Non-Executive Directors and all other relevant stakeholders, of unexpected death or other serious incidents that may attract media attention.
- Providing appropriate advice and support to the Chief Nurse and Medical Director to enable the accurate identification, reporting and investigation of serious incidents.
- Liaising with the Trust's Communications Manager on any incidents that may result in media interest.
- Obtaining appropriate management reports from the responsible manager in the event of a potential or actual serious incident.
- Instigating serious incident investigations and other internal investigations/reviews in line with this policy and published best practice guidance.

- Ensuring an effective quality assurance process is in place to monitor the quality of investigations, associated reports and action plans prior to submission to the Board of Directors or designated sub-committee, and commissioning body.
- Ensuring an effective tracking system is in place so that progress against action plans arising from serious and other grades of incident can be monitored and reported on to the Board of Directors.
- Ensuring assurance evidence is collected and appropriately stored to validate the implementation of recommendations and actions arising from serious incidents.
- Ensuring assurance evidence can be retrieved in a timely way when required by the Board of Directors or other internal or external stakeholders, as appropriate.
- Analysing incident data to produce performance, management and assurance reports including a six-monthly thematic analysis of serious incidents to the Quality and Safety Group.
- Alerting the appropriate director, manager, consultant, specific department or governance forum if any trend(s) is identified from reported incidents.

Should a **Never Event** occur, all reporting documentation will clearly indicate 'Never Event'. This policy is to be followed with the following additions:

- Chief Executive or Executive Officer on call must be informed immediately
- Never Event reported via STEIS and the NRLS within one working day
- Responsible consultant and CCG management team to be informed immediately

The Chief Nurse will meet these duties through the Head of Governance and Risk and his/her team.

5.4 Medical Director and Chief Nurse

The Medical Director and Chief Nurse are responsible for ensuring that their respective professional groups are compliant with this policy and associated procedures in identifying, reporting and investigating incidents. This includes a responsibility to ensure professional practice obligations are maintained, learning is shared and any necessary changes implemented following the investigation of incidents.

They will also provide professional advice and contribute to the decision making processes to identify serious incidents.

5.5 Executive Directors

All executive directors are responsible for ensuring incident reporting arrangements as described in this policy are implemented throughout their service areas.

5.6 Medical Directors Office

The Medical Directors Office will co-ordinate specific workstreams related to the clinical needs of the organization to support its current and future service delivery, as directed by the Medical Director. Initiatives will be derived from areas where SIs or other adverse events indicate that improvements in clinical standards in relation to the quality and safety of patient care are required.

5.7 Head of Governance and Risk

The Head of Governance and Risk has delegated day-to-day management responsibility for the Trust's electronic incident management system together with all other systems related to the recording, analysis and tracking of incidents, serious incidents and associated action plans. The post holder will ensure all such systems are kept up to date with the latest software releases, and that changes and improvements are shared with systems users as appropriate. The Head of Governance and Risk must ensure systems are fit for purpose and capable of

producing the information required by the Board and its sub-committees, executives and all other senior managers of the Trust in a timely way.

The Head of Governance and Risk will inform, via email, the following Trust staff whenever a SI is reported/identified by either the Chief Executive or the

- Medical Director;
- Chief Nurse;
- Business unit/Divisional management team where serious incident occurred;
- Divisional Risk and Patient Safety Managers
- Head of Communications;
- Non-Executive directors.

In the event of a SI, the Head of Governance and Risk will recommend a Lead Investigating Officer (IO) who is appropriately trained and experienced to lead the serious incident investigation to the appropriate Executive Director for approval.

The Head of Governance and Risk will inform the following Trust staff where appropriate:

- Head of Midwifery;
- Head of Safeguarding (adult or children);
- Head of Infection Control and DIPC;
- Chief Pharmacist;
- Accountable Officer (AO) for Controlled Drugs

The decision to investigate an incident by either a Serious Incident or Internal Safety Alert (ISA) process lies with the Business Unit,. Following confirmation from the Business Unit the Governance and Risk Department will inform the appropriate commissioning body and record the incident on the electronic Strategic Executive Information System (STEIS), and work with the lead IO and Business Units to ensure a robust investigation is undertaken and that an approved report and action plan is submitted to the Trust's commissioners within **60 working days including Never Events** from reporting on STEIS.

The Head of Governance and Risk, through their team, will oversee the completion and submission of reports and action plans, together with tracking completion of actions. Evidence should be uploaded to Datix for internal and external inspection, as required.

5.8 Divisional Risk and Patient Safety Managers

The Head of Governance and Risk will ensure that the Divisional Risk and Patient Safety Managers support the Division in the incident reporting, investigation systems and controls in the division. This includes providing information to the Business Units on:

- Monitoring all Key Performance Indicators (KPIs) related to the investigation and closure of all incidents, including SIs.
- Providing data and analysis of incidents using the Trust's incident reporting systems as required by Business Unit senior management teams and other staff groups by providing reports on themes and trends, highlighting areas of potential concern, and correlating information from incidents
- In the event of a SI, supporting the lead investigating officer throughout the investigation process such as:
  - Coordinating and recording notes of meetings
  - Contributing to interim reports as required by the Governance and Risk team

- Support the population and approval of action plans arising from incidents
- Follow up actions and provide evidence to support their achievement to the Governance and Risk Team as required

- Support the Business Unit to ensuring Internal Safety Alert (ISA)s are investigated and reported in accordance with this policy.

5.9 Communications Manager

The Communications Manager will facilitate and coordinate any communications with the media in accordance with the media relations' protocol described within the Trust's Communications Strategy.

5.10 Clinical site management team – out of hours only

If a serious incident or never event occurs out of hours, during a weekend or bank holiday, the on call Clinical Site Practitioner will be contacted immediately by the person in charge of the area where the incident occurred, and will be responsible for informing the on call senior manager who will in turn inform the on call Executive.

The Clinical Site Practitioner will inform the Consultant on call if the incident is a medical incident. The Clinical Site Practitioner will ensure the incident is reported using the Trust's Ulysses/Datix system and will inform the Head of Governance and Risk immediately the next working day via email or telephone. The Clinical Site Practitioner will also inform the Consultant on call in the event of a medical incident.

5.11 On Call Manager – out of hours

Once alerted by the Clinical Site Practitioner, the on call manager will notify the executive on call immediately that a potential serious incident has occurred. The on call manager will ensure that any necessary action is taken in accordance with this policy and process, described in the process map at Appendix 2. Should the on call manager be off site at the time of this notification, they will visit the site at their discretion, depending on the nature and severity of the incident.

The on call manager will keep the Clinical Site Practitioner fully informed of all decisions and actions to be taken.

The on call manager will contact a member of the divisional senior management team at the end of the out of hours on call duty, by the next working day.

5.12 Executive on call – out of hours

During out of hours, the executive on call will be notified by the on call manager of any potential serious incident and will determine whether the incident falls under the definition of a serious incident. The executive on call will receive assurance via the on call manager that the immediate response to the incident has been carried out in accordance with this policy and procedure.

On the next working day, the executive on call will liaise with the Head of Governance and Risk to ensure the incident has been properly reported via Ulysses/Datix and identified as a potential serious incident.

5.13 Lead Investigating Officer (IO)

In the event of a serious or Internal Safety Alert (ISA), the Business Unit will identify an appropriately trained lead IO. The IO will be provided with clear terms of reference within which to conduct the investigation, approved by the Business Unit

The lead IO will facilitate a Root Cause Analysis (RCA) investigation and compile a report using the NPSA templates which are available on the Governance Intranet site All SIs will require a investigation and report. The lead IO and Business Unit should

gain assurance that all staff involved in the incident and who may be interviewed are receiving the appropriate support, including junior doctors.

The lead IO will provide documentary evidence in support of the investigation findings and conclusions for safekeeping by uploading the information to the incident form on Datix.

The draft report will be shared with the Business Unit so that a comprehensive action plan is developed that meets the recommendations from the report findings.

The Accountable Officer of the action plan will monitor the implementation of the action plan until it is completed and agreed at the Serious Incident Review Group meeting.

The Business Unit Lead IO will work with an action plan lead (APL) designated by the Business Unit to complete a comprehensive action plan that meets the recommendations from the report findings. Following approval, the lead IO feeds back findings to the relevant staff group to maximize the opportunities for learning.

The lead IO is expected to conduct the investigation in line with the timescales set out in Appendix 2.

The Business Unit/Lead IO will communicate with the patient/family/carer at the outset of the investigation, informing them of the incident and invite them to make a contribution. A copy of the final approved report will be shared where required in line with the Trust's Being Open policy and the requirement for Duty of Candour.

All trained lead investigating officers should complete a minimum of two SI or Internal Safety Alert (ISA) investigations each year in order to maintain their skill set.

5.14 Divisional Medical Directors

Divisional Medical Directors along with Divisional Directors and Divisional Nurse Directors are accountable for the quality and safety of the services provided within their division. Each Divisional Medical Director has a joint responsibility therefore to ensure the principles and practice described in section 1.0 of this policy is embedded within their division through clear communication with medical staff and effective Quality Governance arrangements.

Where an incident involves a junior doctor in any way, the Divisional Medical Director should ensure the Postgraduate Clinical Tutor is aware so that appropriate support and guidance can be provided to the individual.

The Divisional Medical Director, where required, will designate an action plan lead (APL) to develop an action plan in response to the investigation. The action plan accountable officer (AO) will coordinate the delivery of the action plan and will act as the key point of contact for the Governance and Risk team for the purposes of monitoring, reporting and providing assurance evidence when actions are completed. The AO may be a member of the Business Unit senior management team or another appropriate member of staff.

5.15 Divisional Directors (ADs) or corporate department equivalent

Divisional Directors along with Divisional Medical Directors and Divisional Nurse Directors are accountable for the quality and safety of the services provided within their division. Each Divisional Director and their corporate department equivalent has a joint responsibility to ensure the principles and practice described in section 1.0 of this policy is embedded within their division/department through clear communication with all staff and effective Quality Governance arrangements.

Divisional Director and their corporate department equivalents are responsible for ensuring the appropriate resources, systems and processes are in place to enable the reporting, proper investigation, and implementation of remedial actions in line with the policy and procedure described within this policy. This includes releasing staff who are trained to lead on serious incident investigations to perform their duties. All RCA trained lead investigating officers should complete a minimum of two SI or Internal Safety Alert (ISA) investigations each year in order to maintain their skill set.

5.16 Divisional Nurse Director

Divisional Nurse Director along with Divisional Medical Directors and Divisional Directors are accountable for the quality and safety of the services provided within their division. Each Divisional Nurse Director has a joint responsibility therefore to ensure the principles and practice described in section 1.0 of this policy is embedded within their division through clear communication with all nursing staff and effective Quality Governance arrangements.

Divisional Nurse Directors and the Head of Midwifery are responsible for the supervision of nursing staff within their division through Matrons, Ward and Senior Sisters. They are expected to use visible leadership support to ensure that patient safety incidents are escalated, reported and investigated on behalf of the Divisional Medical Director. Divisional Nurse Directors and Head of Midwifery will be the first point of contact with the Governance and Risk team on patient safety matters. This will include:

- Providing assurance evidence of rapid response reactions, i.e. measures taken against immediate threats to safety or serious issues that need fast tracking
- Contributing to progress update reports as appropriate
- Contributing to Internal Safety Alert (ISA) and serious incident root cause analysis investigations
- Ensuring all reporters of patient safety incidents receive an acknowledgement and are made aware of any actions arising from incidents

Using specific findings and trend analysis from patient safety incidents they are responsible for:

- Identifying all learning opportunities and widely publicizing corrective actions required or taken, including changes in nursing and midwifery policy and practice
- Acting as the designated action plan lead (APL) where required by the Divisional Director to oversee and provide assurance evidence that action plans have been achieved within the agreed timeframe.

5.17 Trust Head of Safeguarding

The Head of Safeguarding is responsible for ensuring the reporting framework for Safeguarding operates and supports the incident reporting policy. The post holder must ensure that all Safeguarding incidents are reviewed and escalated in accordance with external Safeguarding procedures and takes part in any investigation where Safeguarding is believed to be a factor.

The Governance Department will ensure that Information required by the Safeguarding Adult Operational Group is made available through Dashboards on Datix

Ensure children's safeguarding alerts are escalated appropriately and reported as a serious incident where the NPSA criteria as set out in this policy are met.

5.18 All Managers

Managers at all levels within the Trust are responsible for:

- Encouraging an 'open and just' culture within their service area.
- Ensuring all staff who report incidents receive an acknowledgement that encourages a positive reporting and risk management culture.
- Ensuring incident reporting arrangements are implemented within their service areas.
- Following an incident, take immediate action within the scope of their remit to prevent recurrence and/or eliminate or reduce any identified risks i.e. make the individual or environment safe.
- In the event of an SI or potential SI, make appropriate notifications to internal stakeholders such as executive directors, Head of Governance and Riskas appropriate, following the process map at Appendix 2.
- Conduct local investigation into all reported incidents at the appropriate and proportionate level.
- In conjunction with the Governance and Risk team, make arrangements to notify any other regulatory body of any incident as appropriate to their service area or function.
- Conduct a risk assessment and notify their line manager of identified risks highlighted by an incident or near miss, where risks cannot be reduced to an acceptable level.
- Provide immediate and appropriate support to staff, patients and families following incidents.
- Sign off completed incident forms for incidents and near misses within their service area, and/or nominate a staff member to do this on their behalf, ensuring that incident report forms and appendices are completed with appropriate information.
- Use information from reported incidents, including analyses of themes and trends, to inform the undertaking and review of risk assessments for their service areas.
- Ensure an appropriate individual(s) within their service area is nominated to sign off incident forms in their absence.

5.19 All staff

- Report all incidents and near misses via the Trust's electronic incident management system, Datix.
- Ensure the details of any incident are contemporaneously and objectively reported in the patient's clinical record.
- Raise any concerns about situations that led to, or could lead to, an incident or a near miss with their line manager, risk management or Governance department or appropriate Trust specialist advisor.
- Actively participate in any subsequent incident investigation such as: providing a written account of the incident; attending multidisciplinary fact-finding and feedback meetings.
- Attend a Coroner's inquest on behalf of the Trust if called to do so.

The Trust will make available appropriate support to those staff involved in a traumatic incident, where this is required.

5.20 Accountable Officer for Controlled Drugs

The Accountable Officer for Controlled Drugs is the Medical Director. In this role, the Accountable Officer will ensure that reports of any incident involving Controlled Drugs is made to the Managing Director of the Area Team, Controlled Drugs Local Intelligence Network (CD LIN) and the police where appropriate.

5.21 Quality Committee

Provider organisations are required to have a relevant committee/mechanism and governance in place to consider and monitor serious incident investigations. The Trust's Quality Committee undertake this role on behalf of the Board of Directors. The committee's terms of reference will include the need to ensure that regular thematic reviews are undertaken to extract learning and support the development of organisational memory and continuous improvement with regard to patient safety. In addition, the committee will have responsibility for receiving appropriate assurance that adequate governance arrangements are in place to monitor the completion of action plans and the subsequent effectiveness of any risk reduction measures introduced.

The committee must ensure that they have oversight of overdue actions on behalf of the Board of Directors and that mechanisms are in place to regularly review changes made as a consequence of learning from serious incidents, to be assured that changes are embedded, sustained and effective. The Committee will recommend those serious incidents that should be considered by the Board of Directors of Directors for follow up once the action plan has been completed.

5.22 Serious Incident Review Group (SIRG)

The SIRG will, through an integrated governance approach, take a lead role on behalf of the Quality Committee to identify lessons learned from Serious Incidents and Internal Safety Alert (ISA)s by being the main forum within the Trust to review investigations reports and oversee the process for management of Serious Incidents and Internal Safety Alert (ISA).

5.23 Trust Executive Committee

The Trust Executive Committee (EMC) ensures accountability from divisions regarding implementation of actions and dissemination of learning following serious and Internal Safety Alert (ISA), or other incident trends highlighting emerging issues. Receive assurance that the Trust's *Being Open* policy and Duty of Candour is adhered to in terms of sharing SI reports with patients or family members through a being open meeting, and with individual staff involved in the incident.

5.24 Quality Committee

The Clinical Management Committee (CMC) is responsible for the initiation and management of cross-cutting patient safety initiatives arising from serious incidents or Internal Safety Alert (ISA), or other themes/trends highlighting emerging issues and provide a forum for shared learning. This includes the dissemination of patient safety alerts and any additional staff training requirements. The Quality Committee may delegate specific work streams to a task and finish group if and when it considers appropriate.

5.25 Divisional Governance Boards

Divisional Governance Boards are responsible for reviewing all serious incident reports, recommendations and actions, together with monitoring the implementation of improvements and clinical specialty shared learning. Commissioning follow-up audits as appropriate to receive assurance that learning has resulted in the changes anticipated.

5.26 Other Committees/Groups with responsibilities for taking account of incidents

- Audit Committee
- Risk Management Committees/Groups
- Patient Experience Group
- Other task and finish/working groups authorised by the Board or its sub-committees.

5.27 Postgraduate Clinical Tutor

When a patient safety incident involves a junior doctor, the Postgraduate Clinical Tutor should be made aware so that the appropriate support can be provided to the individual. Junior doctors will receive incident training as part of their induction. This will include their responsibilities to report patient safety incidents as well as how they may gain support should they be involved in any way; for example, guidance on writing and submitting witness statements and an explanation of the Coronial process.

6. PROCEDURE

A process map is available at **Appendix 1** to assist all staff reporting or investigating an incident. Should the incident be identified as a potential serious incident or Internal Safety Alert (ISA), the process map at **Appendix 2** will be used. The process maps are designed to provide a quick but comprehensive guide to those reporting and those providing an immediate response to an incident as well as others who may be involved in incidents, such as: the executive team, Clinical Site Practitioner, those responsible for a patient's care, named contact for patient/family/carer liaison, incident managers, investigating officers, action plan leads, the executive team and the Governance and Risk team. **Readers of this procedure are therefore recommended to refer to the relevant process map at this stage as it will help inform understanding of the procedure described in this section.** Not all elements of the process that relate to the Governance and Risk department are described in narrative. These will be captured in local standing operating procedures.

6.1 Immediate response following an incident or near miss event

Not all incidents are serious nor cause harm. Staff should therefore take a proportionate response according to the impact of the incident and level of harm caused. In order to maximise learning from all incidents however, even those that have not caused hard or are 'near miss' incidents, should be reported as described in **Appendix 1** and section 6.3 using the Trust's electronic incident reporting system.

In all instances, the first priority of anyone involved in an incident is to ensure the needs of individuals affected are attended to, including any urgent clinical care that may reduce the harmful impact. The risk of recurrence should be considered immediately and actions taken to mitigate in advance of any investigation.

Where relevant, a safe environment must be re-established, all equipment or medication quarantined, labelled and isolated, and all relevant documentation copied and secured to preserve evidence to facilitate the investigation and learning. To maintain product liability, no piece of equipment should be returned to the manufacturer for repair/examination until the Trust has carried out all necessary tests on the equipment as suggested by the MHRA.

- Measurement, drawings or photographs of the location of the incident should be taken if necessary, appropriate and practical.
- The needs of patients and their family/carers must be made the first priority.
- Relevant documentation should be copied and secured to preserve evidence and facilitate investigation and learning.
- If there is a suggestion that a criminal offence has been committed, the organisation should contact the police. A procedure for the management of the first 48 hours following a potential serious incident is attached at Appendix 2.

If the incident is a potential serious incident, notification must be made to the appropriate Director or their corporate department equivalent, Medical Director or

Head of Nursing. The member of the divisional senior management team will then alert the Head of Governance and Risk who will escalate to the Chief Executive and Director of Governance to agree grade and external reporting arrangements. The Serious Incident Review Group will commission an investigation proportionate to the type and seriousness of the incident, setting terms of reference for the investigating officer. Out of hours (17:01 – 08:59) the Clinical Site Practitioner is the first point of immediate contact as described in Appendix 2.

Where a serious incident raises concerns in relation to an individual's capability or competence, the staff member must be treated with care and consideration and supported within the principles of a 'just culture'. Staff involved or affected by the incident should be supported in line with the Trust's Supporting Staff Policy. The **Incident Decision Tree at Appendix 10** is a helpful tool for managers and senior clinicians to:

- Decide whether it is necessary to suspend staff from duty following a patient safety incident;
- Explore alternatives to suspension, such as temporary relocation or modification of duties; and
- Consider other possible measures to be taken as the investigation progresses.

The Incident Decision Tree is a national tool, designed is to help move away from attributing blame and instead focus on finding the cause when things go wrong, promoting fair and consistent staff treatment between healthcare providers.

Where more than one organisation is involved in a serious incident, the relevant commissioner will be responsible for deciding who will act as the lead organisation for the purposes of investigation and incident management, and be responsible for reporting the incident.

6.2 Being Open and the Duty of Candour

Patients and/or their families (as appropriate) should be informed about patient safety incidents that result in **moderate harm, severe harm or death** and receive appropriate apologies, be kept informed of investigations and be supported to deal with the consequences. This does not apply to low/no harm incidents. In these cases it is left to the judgment of the professional involved in their care or their supervisor.

In cases where the **patient or their family/carer should be informed** then this should occur **within at most 10 working days of the incident being reported.** The initial notification must be verbal (face to face where possible) unless the patient cannot be contacted in person or declines notification. Language barriers, communication difficulties, relevant disability and any other circumstances that will affect the ease of communication must be taken into account.

It may initially be unclear whether a patient safety incident has occurred, or what degree of harm was caused. This is not a reason to avoid disclosure. This conversation is the responsibility of the Lead Clinician however it may be appropriate for another member of staff to speak to the patient or their family on the clinician's behalf. The Trust's *Being Open* policy sets out the responsibilities of a named contact who is identified to provide information and support to the patient and family/carers in the event of a patient safety incident. A step-by-step explanation of what happened, in plain English, based on the facts, must be offered as soon as is practicable. This includes the provision of support to patients, relatives and carers and staff involved in the incident such as information regarding any support systems that are available to patients/relatives/visitors/contractors. Responsibilities include ensuring the *Being Open* conversation with the patient and/or family is clearly

documented in the incident record in the Ulysses/Datix system and that details of the incident are recorded in the patient's individual record.

Information that emerges during an investigation or subsequent to the initial explanation must be offered to patients and their carers/families as soon as is practical. It is helpful to establish regular updates with affected individuals. Any incident investigation reports must be shared **within 10 working days of being signed off as complete and the incident closed** by the commissioner. This includes action plans and the details of investigations and means **the actual written reports** and, if necessary, plain English explanations of their contents.

The Duty of Candour is now a contractual obligation for the Trust and failure to comply may result in a substantial financial penalty.

6.3 Reporting the incident – local level

Managers of all service areas will have arrangements in place to ensure this policy is implemented. This includes ensuring that all members of staff have received the appropriate training to enable them to identify and report incidents using the Trust's incident management system. The process map at Appendix 1 sets out the process and timescales for reporting when an incident is identified. All incidents must be reported immediately upon discovery.

The Trust uses the Ulysses/Datix web based electronic incident system for the reporting and management of all incidents.
All relevant sections of the incident form are to be completed, including:

- A description of who was involved
- What happened
- Incident grading
- Details of the local investigation
- The local immediate actions taken and further actions necessary

Any member of staff can complete an electronic incident report for incidents and near misses involving them, a colleague, a patient, visitor or contractor, or any other person or agency affected by the Trust's activities. The incident report is to be prepared by the member of staff who first became aware of the incident. Managers or a person they nominate in their absence will acknowledge the incident via the electronic reporting system. The purpose of this is to recognise the incident occurred, ensure that appropriate follow-up to the incident is undertaken, including investigation at the appropriate level and satisfactory closure on the Ulysses/Datix system. Incomplete incident forms and incidents 'open' beyond the agreed timescale for investigation will be followed up by the Governance and Risk team with the manager of the department where the incident was reported.

Those to whom incidents are escalated must take responsibility for debriefing the reporter ('bounce back information').

6.4 Incident documentation

Details of a patient safety incident must be recorded contemporaneously and objectively within the patient's individual record. Incident forms however are a management document and copies must not be filed in clinical records. Incident reports are disclosable documents in the event of a claim against the Trust. It is therefore essential that facts only, not opinions, be documented. It should be noted that completion of an incident form does not constitute an admission of liability of any kind.

6.5 Reporting potentially serious incidents

All managers will ensure notifications of unexpected deaths and all other serious incidents or potential serious incidents are made as soon as possible after the event to the Head of Governance and Risk, Divisional Director or their corporate department equivalent, Divisional Medical Director or Head of Nursing relevant to the service area concerned, on call manager via the Clinical Site Practitioner if out of hours, and the Governance and Risk team.

If a serious incident or never event occurs out of hours, during a weekend or bank holiday, the on-call Clinical Site Practitioner will be contacted immediately by the person in charge of the area where the incident occurred, and will be responsible for informing the on call senior manager who will in turn inform the on-call Executive.

The Clinical Site Practitioner will inform the consultant on-call if the incident is a medical incident. The Clinical Site Practitioner will ensure the incident is reported using the Trust's Ulysses/Datix system and will inform the Head of Governance and Risk immediately the next working day via email or telephone. The Clinical Site Practitioner will also inform the consultant on call in the event of a medical incident.

6.6 Local post-incident reporting – Serious Incidents (SIs)

Sometimes initial incident reports do not include sufficient information to allow the Chief Executive to make a decision on the grade of a potential serious incident. Where this is the case a divisional representative may be asked provide a brief rapid response report in conjunction with the local manager for the service where the serious incident occurred.

The serious incident reporting and investigation process map at **Appendix 2** should be referred to for details of how serious incidents should be managed, reported, investigated and actions followed up.

6.7 Safeguarding incidents – Children or Adult at Risk

If the incident is a potential child or adult at risk concern, the member of staff should ensure this is reported in accordance with the Trust's Safeguarding Policy and Procedures. The flowchart at **Appendix 3** should be referred to when an incident suggests a potential adult at risk concern. This shows the interface between the Governance and adult at risk process and provides detailed guidance on the management of an adult at risk concern within the Trust. **Appendix 4** provides guidance relating to a potential child-safeguarding incident and must be followed wherever a member of staff sees evidence that raises a concern of this nature. The chart includes contact telephone numbers, including out of hours and out of area.

6.8 Incidents of fraud or suspected fraud

In the event of fraudulent or suspected fraudulent activity, the Local Counter Fraud Specialist is to be notified immediately. Reference must be made to the Trust's Counter Fraud policy for guidance on how to report and manage this category of incident.

6.9 Incidents of violence and aggression

Any incident where physical contact was made with a member of staff in a violent or aggressive manner must be reported, including incidents where the clinical condition of a patient may be a factor. Refer to the Conflicts Resolution Policy, for further guidance regarding security management and management of violence risks.

6.10 Incident closure

The criteria for judging an incident to be 'closed' will be proportionate to the grade of the incident. For example, incidents graded at 1 to 3 will require the incident manager to provide a full response to be entered onto the Ulysses/Datix incident

management and reporting system, setting out all actions taken, investigation findings, lessons learned and any further action required.

Where the incident is judged as a Internal Safety Alert (ISA) (see Glossary in section 16 for the definition of 'Internal Safety Alert (ISA) ') or a serious incident requiring investigation (SI), then the Governance and Risk team will apply the following closure checklist:

- An appropriate investigation has been completed that identifies findings based on root causes/contributory factors, recommendations and learning opportunities.
- A satisfactory action plan with actions points to address each recommendation and with a named lead and timescale for implementation.
- **Level 1 (Concise) RCA investigation:** evidence demonstrating that local monitoring arrangements are in place to ensure action points are going to be implemented is sufficient.
- **Level 2 (Comprehensive) RCA investigation:** evidence demonstrating that each action point has been implemented is required by the Governance and Risk team. However, where actions are essentially continuous or long-term, an action plan can be considered to be implemented and the SI can be closed when the relevant actions to address these long-term issues have been initiated. This will be subject to the Trust's lines of accountability and governance and reporting framework. This decision can only be taken at the discretion of the Trust's executive.
- Evidence of lessons learned, including partners or stakeholders with whom the learning has been shared including closure approval from the commissioner.
- Full completion of the STEIS record covering all the above points e.g. Date investigation completed, population of RCA/Lessons learned field and;
- A summary of each never event must be provided to the commissioner for inclusion in their annual reporting arrangements.

The designated action plan lead (APL) will provide the key point of contact for the Governance and Risk team.

7.0 NOTIFICATIONS

7.1 Notification to internal and external stakeholders, agencies and regulatory bodies (See section 4 and Appendix 17)

Upon receipt of a completed incident report, the Governance and Risk team will ensure the appropriate internal and external stakeholders; agencies and regulatory bodies are informed as appropriate.

All identified serious incidents must be notified to the relevant bodies without delay and within two working days of the incident occurring (see Appendix 2). It is the role of the Governance and Risk team to ensure that incidents and serious incidents are reported to NHS England via the National Reporting and Learning System (NRLS); to the Care Quality Commission (CQC) as required by the Health and Social Care Act 2008; to NHS Improvement as the Trust's licensing authority; and to the Trust's commissioners via the Strategic Executive Information System (STEIS) within the required timescales.

Appendix 17 sets out the full external reporting requirements for NHS provider organisations.

7.2 Never Events

In the case of a never event, all reporting documentation must clearly indicate 'Never Event' throughout.

- If a never event occurs out of hours, at weekends or bank holidays, the reporter must inform the Clinical Site Practitioner who will inform the senior manager on call. The senior manager on call will then inform the executive on call.
- The executive on call will confirm via e-mail to the Chief Executive, Director of Governance and the Head of Governance and Risk of the never event.

8.0 INVESTIGATING THE INCIDENT

All incidents and near misses will be subject to a level of investigation proportionate to their severity. The appropriate manager will grade all incidents according to the severity of the incident and likelihood of recurrence. The Trust's risk grading tool (5 x 5 risk matrix) must be used to establish the grading of incidents (Appendix 9).

The initial investigation should aim to identify why the incident occurred. Depending on the initial grading and findings from a local investigation, a decision will be made as to whether further investigation is required. As a general rule, all incidents graded 5, where harm has occurred, will be the subject of a comprehensive investigation using root cause analysis (RCA) techniques however in some cases a concise approach will be appropriate. These will be graded as serious incidents requiring investigation (SI) if they meet the criteria and will be reportable to the Trust's commissioners, NHS England, the Care Quality Commission (CQC) and Monitor. If an incident is considered significant but does not meet the serious incident threshold it will be classified as a Internal Safety Alert (ISA) and a concise investigation completed. The full definition of a Internal Safety Alert (ISA) is explained in the Glossary, section 16.

8.1 Requests to provide witness statements in relation to incident investigations and inquests

Where the incident is serious, the manager responsible for the area where the incident occurred should make arrangements for all staff to document their recollection of the incident. This statement will be important should a root cause analysis investigation be required. The member of staff should sign their statement.

Although a signed statement is not a specific requirement in the instance of an incident investigation, there may be circumstances where an external body requires formal, signed statements such as HM Coroner or the Police. It is therefore considered good practice for staff to sign all statements.

Staff must immediately direct all correspondence in relation to inquests or potential claims for compensation to the Legal Services Department, without responding. This includes any request received by a member of staff directly from HM Coroner, Coroner's Officer or Police to provide information relating to an inquest or investigation. The Legal Department are then able to support and advise staff on the course of action to be followed.

8.2 Local responsibility for investigations

Where an incident is graded between 1 and 3 using the Trust risk matrix (i.e. it does not meet the threshold for a Internal Safety Alert (ISA) or serious incident), the member of staff in charge of the area where the incident occurred is required to investigate the circumstances. Findings and learning from local incidents will then be recorded in the appropriate field on the Ulysses/Datix system alongside the incident. The local manager is responsible for ensuring all changes are made and learning

shared with staff in response to incidents to reduce the risk of recurrence. The Divisional Risk and Patient Safety Managers monitors and reports on the KPIs and effectiveness of controls associated with this process.

8.3 Internal Safety Alert (ISA) **investigations**

Where an incident is graded as a Internal Safety Alert (ISA) (see definition in Glossary – section 16), validated by the Head of Governance and Risk, an investigating officer will be appointed from within the division where the incident occurred. The individual should however be a member of staff from an area other than where the incident occurred. An investigation will be conducted and the completed report and completed action plan submitted to the Governance and Risk team who will store this information. Retaining evidence to support actions is the responsibility of the division and will be subject to periodic audit. (See Appendix 2 – Internal Safety Alert (ISA) process map)

8.4 Serious Incident (SI) investigations

Where an incident however is graded as a serious incident (risk matrix grade either 4 or 5) then the Head of Governance and Risk will appoint an investigating officer from the cohort of approved Trust staff trained in RCA techniques. Wherever possible, the lead investigating officer should not be a member of divisional staff where the incident occurred to ensure objectivity is maintained.

8.5 Pressure ulcer investigations

All pressure ulcers identified on admission and those that develop while in hospital must be assessed, recorded, photographed and incident reported with an appropriate investigation initiated into identifying the root cause, for those deemed to have been acquired in hospital. Consideration should be given to raising a safeguarding alert for ulcers identified on admission.

Grade 2 pressure ulcers will be subject to a review to determine avoidability, which is recorded on Ulysses/Datix at the point of the incident report. Grade 3 and 4 ulcers are classified as Internal Safety Alert (ISA) (initially until determined if meets the SI NHS England Definition and then will be escalated to an SI) and must be investigated using the full Pressure Ulcer RCA process with a comprehensive report (See Governance Intranet page) completed and submitted to the Governance and Risk team. It is also important that any learning from pressure ulcers is shared among colleagues to reduce the risk of further incidents. The process map for the incident reporting and investigation of pressure ulcers can be found at Appendix 8.

8.6 Healthcare Associated Infections (HCAI) investigations

It is considered unacceptable for a patient to acquire an MRSA bloodstream infection while receiving care in a healthcare setting. In order to support providers of care to deliver a zero tolerance approach on MRSA BSI there is a requirement to instigate a Post Infection Review (PIR). This process replaces the requirement to undertake Root Cause Analysis. The aim of the PIR is to identify how a case occurred and identify the actions that will prevent it from reoccurring. A multidisciplinary clinical team that will review the case and the contributing factors must conduct the PIR.

The outcome of the PIR will be to attribute responsibility for the case, and relies on strong partnership working by all providers involved in the care of the patient. It is the responsibility of the organisation where the case is identified to ensure that information is submitted within 21 days of notification. In order to comply with this the PIR must be undertaken promptly.

The Appendix 6 and 7 process maps taken from *Guidance on the reporting and monitoring arrangements and post infection review process for MRSA bloodstream*

infections from April 2013 outline the process for completing the PIR and the reporting arrangements.

8.7 Lead Investigating Officer (IO) responsibilities (Appendix 15)

An appropriately trained lead IO will be appointed by the Head of Governance and Risk. The IO will be provided with clear terms of reference within which to conduct the investigation, approved by the Serious Incident Review group. The lead IO will lead a team of appropriately qualified and experienced individuals to provide expert advice or support to the investigation. The Divisional Risk and Patient Safety Managers will ensure that appropriate records and evidence are maintained, and advise the lead IO on all stages of the SI investigation process. This will include ensuring the clinical records and any evidence are secured at the earliest opportunity and that the relevant section of the clinical record is copied and made available to the lead IO.

The lead IO will facilitate a Root Cause Analysis (RCA) investigation at a level proportionate to the incident (see Appendix 12) and compile a report using the NPSA template (Appendices 14 and 15). Unless otherwise advised all SIs will require a comprehensive (level 2) investigation and report.

In addition to the report, the lead IO will maintain accurate records and an audit trail in support of the investigation findings and conclusions including the following documents:

- All statements received from those involved in the incident and investigation
- Any other supporting evidence used as part of the investigation
- A record of any meetings conducted during the investigation (supported by the Governance and Risk team)
- A completed chronology of the incident
- All completed analysis tools such as fishbone charts used to establish contributory factors and root cause(s)

The draft report will be quality assured by the Head of Governance and Risk before being recommended to the Serious Incident Review group. The final approved version will then be submitted to the Trust's commissioners in line with the requirements of the annual contract, and shared with the lead IO and the divisional senior management team for distribution as appropriate.

The Lead IO will work with an action plan lead (APL) designated by the divisional senior management representative to complete a comprehensive action plan that meets the recommendations from the report findings. Following executive approval, the lead IO feeds back findings to the relevant staff group to maximize the opportunities for learning.

The lead IO is expected to conduct the investigation in line with the timescales set out in Appendix 2.

9.0 REPORTING ON INVESTIGATIONS

9.1 Root cause analysis (RCA) investigation report

In the case of Internal Safety Alert (ISA) and serious incidents the lead investigating officer is responsible for completing a draft report using the appropriate Trust template (Appendices 10, 14 and 15)

If a serious incident has also been subject to an inquest then the coroner's verdict must be included in the final report if available at the time of writing.

9.2 All incidents graded 1 – 3

These incidents must be investigated locally and the appropriate information captured in the incident management system. The following timescales will be incorporated into divisional key performance indicators (KPIs).

- Maternity incidents – 5 days
- All other incidents – 5 days

9.3 Reporting timescales – Internal Safety Alert (ISA) and Serious Incidents

Once the investigation is completed an RCA investigation report will be submitted to the Governance and Risk team within 45 working days of the incident, accompanied by an action plan that has also been approved through the Business Unit governance framework. The RCA investigation report and action plan will be received at the Serious Incident Review Group and presented by the Lead IO and Action Plan AO for approval.

Internal Safety Alert (ISA) - Once the RCA investigation report and action plan have been approved they can now be offered to the patient/family to meet the Duty of Candour requirements. The action plan will continue to be monitored through the Serious Incident Review Group Action Plan meeting until completion

9.4 RCA Serious Incident report approval

Once the RCA investigation report and action plan have been approved the Governance and Risk Department will submit to the Trust's commissioners (CCG and Virgin Care) for approval. The RCA investigation report and action plan can only be offered to the patient/family once the documents have been approved by the commissioners.

The final signed off report with action plan must be forwarded to the commissioners within **60** working days of the STEIS report.

9.6 Action plans

All action plans, whether arising from a Internal Safety Alert (ISA) or serious incident, are the responsibility of the area where the incident occurred to implement and monitor, coordinated by the Accountable Officer.. Exceptions to this would be where the changes required the involvement of more than one division . This will be clear from the allocation of responsibilities within the action plan.

9.7 Tracking and assuring actions

The implementation of the action plan following serious incident investigations and Internal Safety Alert (ISA) lies at a Business Unit level. However, it is the responsibility of the Governance and Risk team to provide a tracking system for **all serious incident action plans** which is available within the Datix system and accessible to the Department and Business Units.. Business Units/departments will be expected to provide regular updates on their achievement against any serious incident/Internal Safety Alert (ISA) action plans, highlighting where actions are overdue or non-achievement of deadlines is anticipated, providing assurance evidence when actions are reported as 'complete'.

All serious and Internal Safety Alert (ISA) action plans must be presented at Business Unit Governance group meetings by the designated action plan accountable officer (AO). The nominated leads, as indicated through the action plan, will be requested to deliver their action(s) within the timescales agreed. Delivery of

actions will be monitored and recorded at the Serious Incident Review Group meeting until completed.

Overall responsibility for this process lies with the management team where the incident occurred. In the event that actions cannot be completed within the given timescale this must be escalated to the divisional management team in accordance with the Trust's risk management framework at the earliest opportunity, and recorded on the appropriate risk register.

It is the responsibility of the divisional management team to ensure that learning from serious and Internal Safety Alert (ISA) is shared with appropriate staff groups, and that recommendations following such incidents are acted on.

10.0 LEARNING FROM INCIDENTS

10.1 Learning lessons

One of the key aims of the serious incident reporting and learning process is to reduce the risk of recurrence. The timely and appropriate dissemination of learning following an SI or Internal Safety Alert (ISA) is core to achieving this and to ensure that these lessons are embedded in practice.

10.2 Definition of learning in the context of patient safety

Learning from a patient safety incident should be a collaborative, decentralised and reflective process that draws on experience, knowledge and evidence from a variety of sources.

- Organisational learning can be demonstrated by sustainable changes and improvements in process, policy, systems and procedures relating to patient safety.
- Individual learning can be demonstrated by sustainable changes and improvements in behavior, beliefs, and attitudes and knowledge of workers at the front line of service delivery.

10.3 Examples of learning

Examples of learning following a patient safety related incident include:

- Changes to strengthen controls within systems and processes that will reduce the potential occurrence or impact of future incidents. This may include for example, modification to patient safety tools or processes such as the WHO safety checklist for theatres, changes to falls risk assessments or drug administration protocols, or introducing additional checks within a routine process such as those undertaken within the Trust's laboratories.
- Changes to individual or collective ways of working to reduce the potential for incidents, errors or omissions. This may include for example making changes to handover routines that standardise the way in which information is exchanged, or changes to the way in which MDT meetings are conducted.
- Sharing solutions to address identified incident root causes and contributory factors that may be relevant to other teams, services or organisations.

10.4 Disseminating learning

There are a number of ways in which learning from a serious or Internal Safety Alert (ISA) might be disseminated within the Trust to improve patient safety and reduce the risk of recurrence. Examples of communication methods might include but are not limited to:

- Presentations and discussion at staff/team meetings.

- E-bulletins and newsletters.
- Trust intranet site.
- Trust public web site.
- Public board papers.
- Patient safety notice boards.
- E-mail/internal alert mechanisms.
- Reports to **Quality Committee** and other related patient safety and risk forums.
- Incorporation into risk management, incident reporting and investigation training i.e. using case studies.
- Performance management review meetings.
- Board and sub-board (Divisional/Business Unit/departmental) governance and assurance mechanisms.
- Quality reporting arrangements.
- Local conferences, seminars and workshops.
- Periodic serious incident and incident summary reports.
- Educational meetings.

Action plans should describe the ways in which learning from the individual incident will be disseminated. Audits will be conducted to strength test the learning/changes required from the serious incident to ensure improvements are being maintained.

10.5 Analysis of incident data

The electronic incident management system (Datix) enables data from reported incidents to be analysed for themes, trends or patterns, and such information will be utilised in the preparation of performance and assurance reports to the Board of Directors, its sub-committees and all other patient safety related committees and groups, as required. All Departmental Managers have access to Datix which enables them to extract their own reports and through their Datix Dashboards.

Incident data will form part of the Trust's aggregated analysis of risk management information. Aggregated analysis involves the collation and analysis of information from different sources such as:

- Incidents
- Serious incidents
- Complaints and PALs
- Claims
- Inquests
- Patient surveys and other feedback
- Clinical audit results

Analysis of incident data is a standing item on divisional and governance meeting agendas. Where a staff or patient safety, or other category of risk is identified from incident data or aggregation of information from other sources, the risk must be graded using the Trust's risk management matrix (5 x 5) for its impact and likelihood. Consideration should then be given to conducting and documenting a formal risk assessment, recording the risk on the Trust's risk register if remedial action cannot be taken to reduce the risk to an acceptable level.

10.6 Risk assessment

Incident and near miss event information will be utilised by managers when conducting or reviewing risk assessments, in accordance with the Trust's Risk Management Procedure.

11.0 COMMUNICATION

11.1 Patients and/or family/carers

In the case of serious incidents, to include all patient safety incidents that result in **moderate harm, severe harm or death**, every step must be taken to ensure that the patient and their family or carers are informed at the earliest opportunity in line with the Trust's *Being Open* policy and the Duty of Candour.

At the 'stop moment' which will be undertaken within 2 days of the incident occurring the Business Unit will agree who will complete the verbal Duty of Candour. It is essential that someone with the necessary understanding of the situation, as well as the appropriate ability to take responsibility, establish contact.

At the point of raising the SI/ISA, the Business Unit will formally identify the contact person best suited to speak to the patient and family to inform them of the pending investigation and subsequent findings.

The Trust representative from the above list should ensure that any questions or concerns raised by patients, relatives or carers are shared with the lead investigating officer and incorporated into the investigation. Staff should understand that an apology when something goes wrong does not constitute an admission of liability.

The Initial Duty of Candour letter will need to be sent out by the Business Unit within 10 days of the incident occurring. Evidence of discussion and letters sent require uploading to Datix by the Business Unit which will but subjected to audit to ensure compliance.

11.2 Sharing the report with patients/families/carers.

Senior staff from the Business Unit involved in the early communication with the patient, family or carers will inform them that the final report will be offered to them. They will be informed that the report is anonymised in order to assist in the appropriate dissemination of learning and to maintain confidentiality. It will be required to establish the appropriate arrangements for the sharing of the report and this may require a further meeting.

11.3 Communication with staff

All staff should receive feedback on incidents they have reported It is the responsibility of the line manager (or their nominated deputy) to provide feedback to the person who reported the incident, thanking them for highlighting the issue, and informing them of the action(s) taken following the event. This process is automated through Datix when incidents are closed. If reporters of incidents are unsure/require further information regarding the incident, this should be discussed with their line manager.

11.4 Media involvement following an incident

It is the responsibility of the Governance and Risk team to inform the Communications Manager in the event of a serious incident. All media enquiries received by individual members of staff must be referred to the Communications team who will respond on behalf of the Trust. The Trust will not notify the media before staff, patients, relatives or the public have been informed. If necessary, staff should refer to the Trust's Communications Strategy.

11.5 Hotline arrangements

In the case of an incident that has affected a large number of individuals who may need either to be contacted by, or who may need to contact the Trust, a dedicated hotline will be set up that is coordinated by the Communications Department. The Communications Department will publish information to staff, patients and the public by the appropriate route. When setting up such arrangements, the Communications Department will need to give consideration to the following:

- Management responsibility
- Media management
- Phone lines
- Internet and intranet information
- Staffing
- Capacity to manage calls over time
- Documentation
- Record keeping
- IT/e-mail and postal arrangements

12.0 CLAIMS FOR COMPENSATION FOLLOWING INCIDENTS

Staff or patients, who have incurred any financial loss due to the theft or damage of clothing or belongings whilst on Trust premises, may wish to claim for the loss. The Trust will not compensate for items that could be covered through normal household contents insurance that covers personal loss. Nor will the Trust accept responsibility for patients' items that were not handed in for safe-keeping. There may be circumstances however where an ex-gratia payment to cover minor damages to clothing or belongings during an incident may be appropriate.

Reimbursement expenses via ex gratia payments will be met from the budget of the service area reporting the loss but all compensation/loss forms must be approved by the Business Unit General Manager before payment is made.

13.0 REPORTING PATIENT OR STAFF SAFETY CONCERNS

It is the duty of all Trust staff to share any concerns about issues that affect staff or patient safety, or other significant issue; either directly with their line manager or through Trust specialist advisors. Staff should also feel free to raise concerns without fear of recrimination through the Trust's Whistleblowing policy, which is available on the Trust's intranet or in discussion with the Trusts Freedom to Speak Out Gardian.

14.0 TRAINING

All staff must receive relevant guidance and training to help them identify, report and investigate incidents appropriate to their role. Healthcare provider organisations are required to include the reporting and management of serious incidents as part of staff induction and ongoing training. Attendance at training will be recorded and reported via the Trust's governance and monitoring framework for training.

15.0 MONITORING COMPLIANCE WITH THIS POLICY

The table below outlines the Trust's monitoring arrangements for this policy document. The Trust reserves the right to commission additional work or change the monitoring arrangements to meet organisational needs.

Minimum requirement to be monitored	Method of Monitoring e.g. audit	Responsible individual group / committee	Frequency of monitoring	Responsible individual group / committee (inc timescales for:		
				Review of results	Development of action plan	Monitoring of action plan and implementation
How the organization trains staff in line with the training matrix	RCA training for specific staff who undertake serious or Internal Safety Alert (ISA) investigations	Director of HR/People Committee	Education and Training Bi-annual Report	People Committee	Head of Governance and Risk	People Committee
Different levels of investigation appropriate to the severity of the event	Audit Executive Review Group minutes. Audit of reports to QPSC and SMG	Quality Committee	Annual	Quality Committee	Head of Governance and Risk	Quality Committee
How the organization shares safety lessons with internal and external stakeholders	Audit Executive Review Group minutes. Audit of reports to QPSC and SMG	Quality Committee	Annual	Quality Committee	Head of Governance and Risk	Quality Committee
How action plans are followed up.	Audit Executive Review Group minutes. Audit of reports to QPSC and SMG	Quality Committee	Annual	Quality Committee	Head of Governance and Risk	Quality Committee

16.0 GLOSSARY

Abuse - A violation of an individual's human or civil rights by any other person or persons. Abuse may consist of single or repeated acts. It may be physical, verbal or psychological, it may be an act of neglect or an omission to act, 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 can occur in any relationship and may result in significant harm, or exploitation, of the person subjected to it (as defined by *No Secrets*, available at:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008486.

In *Working together to safeguard children (2010)* abuse is defined as follows: 'abuse and neglect are forms of maltreatment of a child. Somebody may abuse or neglect a child by 'inflicting harm' or by failing to act to prevent harm'.

Adverse Event/Incident - See Patient Safety Incident.

Being Open - Open communication of patient safety incidents that result in harm or the death of a patient while receiving healthcare.

Carers - Family, friends or those who care for the patient. The patient has consented to their being informed of their confidential information and to their involvement in any decisions about their care.

Child - The Children Act 1989 and the Children Act 2004 define a child as being a person up to the age of 18 years. The Children Act 2004 states that safeguarding, protection and

cooperation between services may, in certain circumstances, be continued through to a young person's 19th birthday or beyond.

Clinical commissioning group - Clinically-led organisation that commissions most NHS-funded healthcare on behalf of its relevant population. CCGs are not responsible for commissioning primary care, specialised services, prison healthcare, or public health services.

Commissioner - An organisation with responsibility for assessing the needs of service users, arranging or buying services to meet those needs from service providers in either the public, private or voluntary sectors, and assuring itself as to the quality of those services.

Internal Safety Alert (ISA) **–** An incident which may or may not meet the published level one serious incident criteria but gives cause for concern. Equally, a series of incidents, irrespective of the level of harm, that suggest an emerging trend. In such cases, it is proportionate to use a concise RCA to ensure there are no unique factors that require further in-depth investigation.
Resources should be focused on implementing improvement rather than conducting comprehensive investigations that will not produce new learning.

Culture Learned attitudes, beliefs and values that define a group or groups of people.

Data Loss There is no simple definition of a serious incident. What may at first appear to be of minor importance may, on further investigation, be found to be serious and vice versa.
Any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious.

Duty of Candour - defined in The Francis report as: '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.'

Equipment - Machines and medical devices used to help, prevent, treat or monitor a person's condition or illness. The term may also be used to refer to aids that may support a person's care, treatment, support, mobility or independence, for example, a walking frame, hoist, or furniture and fittings. It excludes machinery or engineering systems that are physically affixed and integrated into the premises.

General Practitioner - A medical practitioner who provides primary care to meet the general health needs of a registered population. General practitioners treat acute and chronic illnesses and provide preventative care and health education for all ages.

Healthcare - The preservation of mental and physical health by preventing or treating illness through services offered by the health professions, including those working in social care settings.

Healthcare Professional - Doctor, dentist, nurse, pharmacist, optometrist, allied healthcare professional or registered alternative healthcare practitioner.

Incident - An event or circumstance that could have resulted, or did result, in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, contractor, volunteers, visitors or members of the public.

Independent Healthcare - Private, voluntary and not-for-profit healthcare organisations that are not part of the NHS.

Investigation - The act or process of investigating – a detailed enquiry or systematic examination.

Major incident (to invoke Major Incident Plan) - An unexpected event that overwhelms normal resources, and that requires special measures. It would be expected to involve a large number of casualties of a variety of severity arriving in a short period of time. Following declaration of a major incident, the Trust's Major Incident Plan is invoked. A serious incident may also require the Major Incident Plan to be invoked. This decision will be made between the Chief Executive or their nominated Deputy in discussion with relevant senior clinicians. Please refer to the Trust's Major Incident Policy for further information.

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').

Medical Device - Any instrument, apparatus, appliance, software, material or other article (whether used alone or in combination) (including software intended by its manufacturer to be used for diagnostic and/or therapeutic purposes and necessary for its proper application), intended by the manufacturer to be used for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, alleviation of or compensation for an injury or disability;
- investigation, replacement or modification of the anatomy of a physiological process;
- control of conception

and which does not achieve its physical intended action on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

Near Miss – Any incident that did not result in injury/ill health or property damage/loss, but which had the potential to do so.

Never Events - Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare provider.

NHS-Funded Healthcare - Healthcare that is partially or fully funded by the NHS, regardless of the provider or location.

Notification - The act of notifying to one or more organisations/bodies.

Patient Safety - The process by which an organisation makes patient care safer. This should involve risk assessment, the identification and management of patient-related risks, the 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. The term 'patient safety' is replacing 'clinical risk', 'non-clinical risk' and the 'health and safety of patients'.

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

Permanent Harm – Harm directly related to the incident and not to the natural course of the patient's illness or underlying conditions, defined as permanent lessening of bodily functions, including sensory, motor, physiological or intellectual.

Primary Care - refers to services provided by GP practices, dental practices, community pharmacies and high street optometrists and commissioned by the NHS Commissioning Board from April 2013

Prolonged pain and/or prolonged psychological harm – pain or harm that a patient has experienced, or is likely to experience for a continuous period of 28 days.

Professional Body - An organisation that exists to further a profession and to protect both the public interest, by maintaining and enforcing standards of training and ethics in their profession, and the interest of its professional members.

Provider (or Healthcare provider) - Organisation that provides healthcare including NHS trusts, NHS Foundation Trusts, general medical practices, community pharmacies, optometrists, general dental practices and non-NHS providers.

Quality Governance - A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

Quality Surveillance Groups - Virtual teams established across a health economy either at the level of the relevant NHS CB area team or regional team, bringing together organisations and their respective information and intelligence gathered through performance monitoring, commissioning, and regulatory activities. By collectively considering and triangulating information and intelligence, QSGs will work to safeguard the quality of care that people receive. http://en.wikipedia.org/wiki/Health_care - cite_note-11#cite_note-11

RIDDOR - the Reporting of Injuries Diseases and Dangerous Occurrences Regulations 1995 (HSE 1999) - RIDDOR defines the type of incidents, diseases and occurrences that must be reported to the Health and Safety Executive to comply with statutory requirements. The full definition for each category of RIDDOR reportable incident is available at the HSE website: http://www.hse.gov.uk/riddor/report.htm

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

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

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.

Safety - A state in which risk has been reduced to an acceptable level.

Safeguarding - Ensuring that people live free from harm, abuse and neglect and, in doing so, protecting their health, wellbeing and human rights. Children, and adults in vulnerable situations, need to be safeguarded. For children, safeguarding work focuses more on care and development; for adults, on empowerment, independence and choice.

Security incident – The following security incidents must be reported to the NHS Security Management Service using the *Security Incident Reporting System (SIRS):*

- Any security incident involving physical assault of NHS staff;
- Non-physical assault of NHS staff (including verbal abuse, attempted assaults and harassment);
- Theft or criminal damage (including burglary, arson, and vandalism) to NHS property or equipment (including equipment issued to staff);
- Theft of or criminal damage to staff or patient personal property;
- Properly damage arising from these types of security incident.

Serious Incident Framework - Supporting learning to prevent recurrence (published 27th March 2015)
Definition of reporting a serious incident has changed which now includes the following definition.
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 occurring10; 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.
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
- Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues
    - Property damage;
    - Security breach/concern;
    - Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
    - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
    - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or
    - Activation of Major Incident Plan
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation

Serious harm:
Severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care);
Chronic pain (continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery); or
Psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days).

Severe Harm - A patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.

Significant Event Audit - An audit process where data is collected on specific types of incidents that are considered important to learn about how to improve patient safety.

Treatment - Broadly, the management and care of a patient, to prevent or cure disease or reduce suffering and disability.

Unexpected Death - Where natural causes are not suspected. These should be investigated to determine if the incident contributed to the unexpected death.

Working Day - Days that exclude weekends and bank holidays.

17.0 ASSOCIATED LEGISLATION AND REFERENCES

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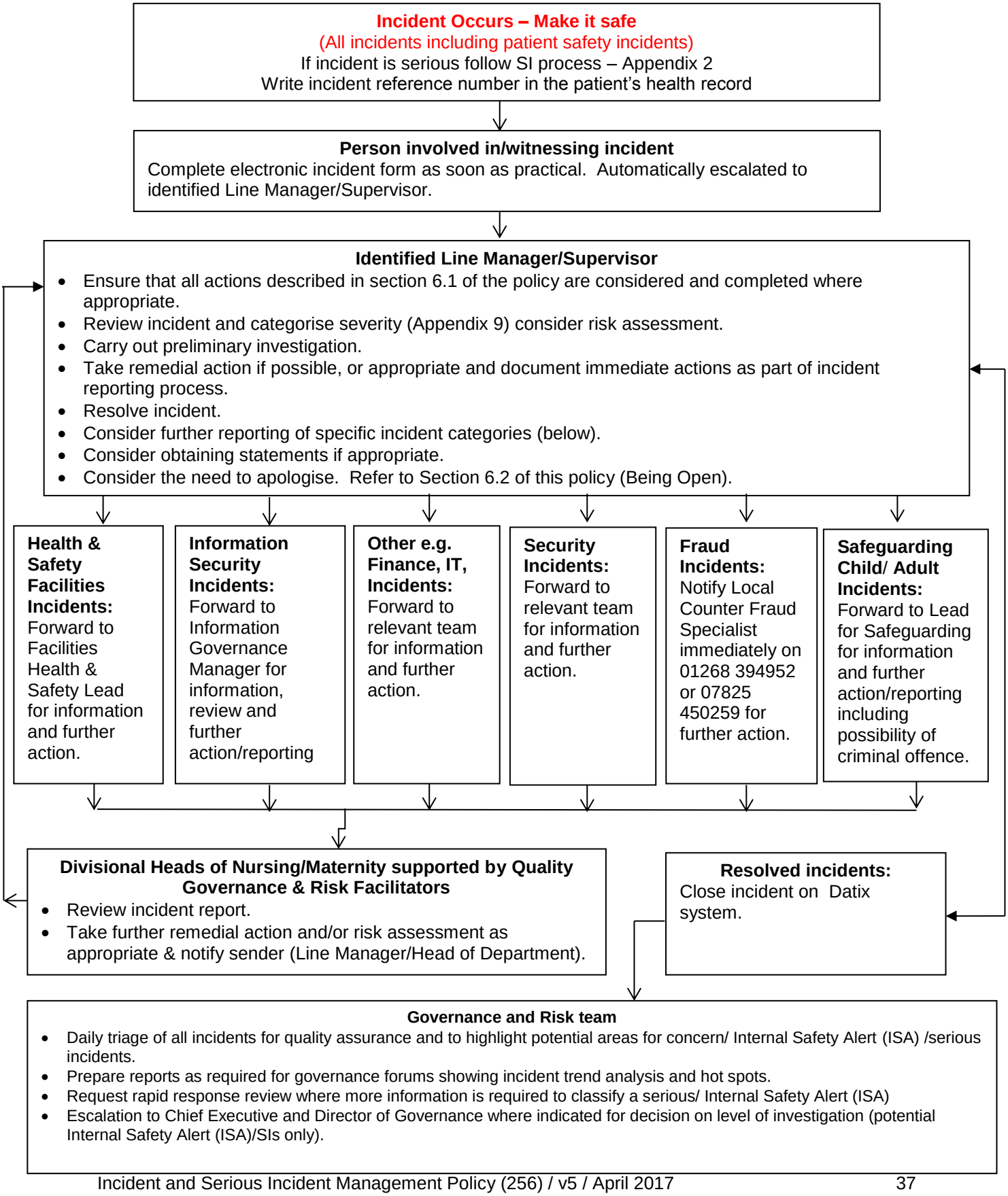
The Essentials of Patient Safety (August 2011). Charles Vincent, Professor of Clinical Safety Research, Imperial Centre for Patient Safety and Service Quality, Department of Surgery and Cancer, Imperial College of Science, Technology & Medicine, London UK. Available at http://www1.imperial.ac.uk/cpssq/cpssq_publications/

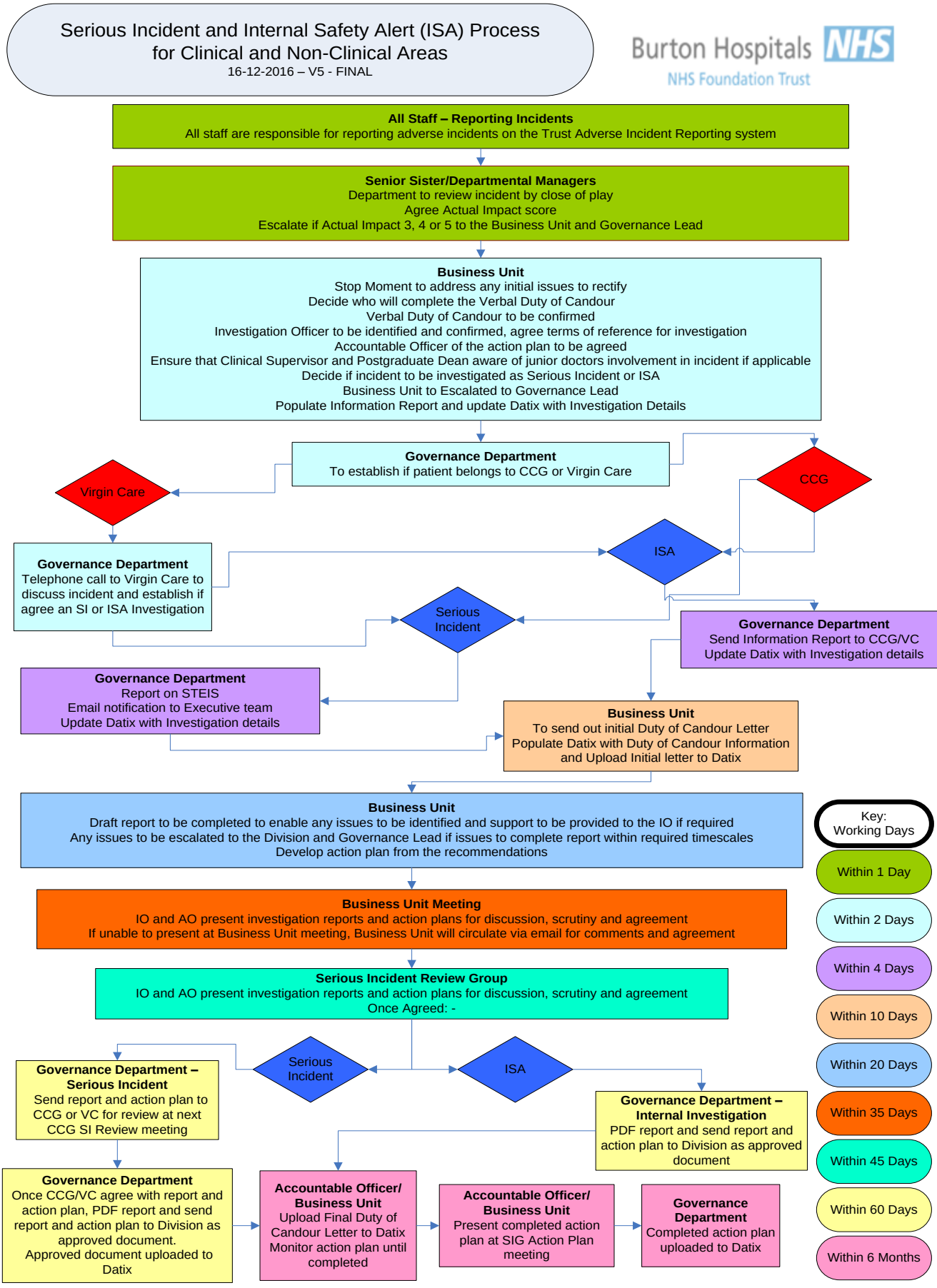
A Promise to learn – a commitment to act: improving the safety of patients in England (6 August 2013). Professor Don Berwick MD. Available at https://www.gov.uk/government/publications/berwick-review-into-patient-safety

APPENDIX 1

BHFT INCIDENT REPORTING AND MANAGEMENT FLOWCHART

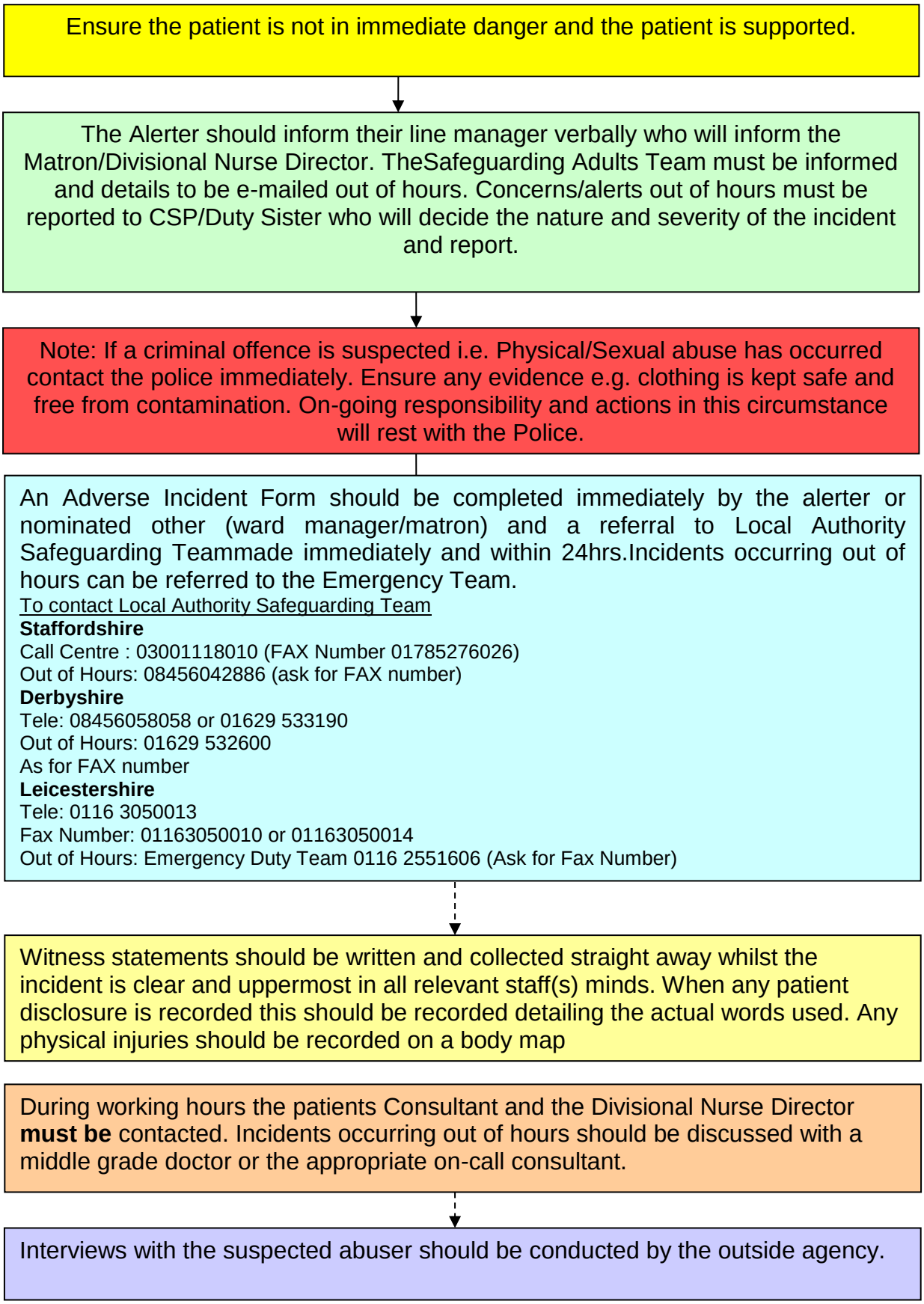


APPENDIX 2


Serious Incident and Internal Safety Alert (ISA) Process for Clinical and Non-Clinical Areas
16-12-2016 – V5 - FINAL
Burton Hospitals NHS
NHS Foundation Trust
All Staff – Reporting Incidents
All staff are responsible for reporting adverse incidents on the Trust Adverse Incident Reporting system
Senior Sister/Departmental Managers
Department to review incident by close of play
Agree Actual Impact score
Escalate if Actual Impact 3, 4 or 5 to the Business Unit and Governance Lead
Business Unit
Stop Moment to address any initial issues to rectify
Decide who will complete the Verbal Duty of Candour
Verbal Duty of Candour to be confirmed
Investigation Officer to be identified and confirmed, agree terms of reference for investigation
Accountable Officer of the action plan to be agreed
Ensure that Clinical Supervisor and Postgraduate Dean aware of junior doctors involvement in incident if applicable
Decide if incident to be investigated as Serious Incident or ISA
Business Unit to Escalated to Governance Lead
Populate Information Report and update Datix with Investigation Details
Governance Department
To establish if patient belongs to CCG or Virgin Care
Virgin Care
CCG
Governance Department
Telephone call to Virgin Care to discuss incident and establish if agree an SI or ISA Investigation
ISA
Serious Incident
Governance Department
Send Information Report to CCG/VC
Update Datix with Investigation details
Governance Department
Report on STEIS
Email notification to Executive team
Update Datix with Investigation details
Business Unit
To send out initial Duty of Candour Letter
Populate Datix with Duty of Candour Information and Upload Initial letter to Datix
Business Unit
Draft report to be completed to enable any issues to be identified and support to be provided to the IO if required
Any issues to be escalated to the Division and Governance Lead if issues to complete report within required timescales
Develop action plan from the recommendations
Business Unit Meeting
IO and AO present investigation reports and action plans for discussion, scrutiny and agreement
If unable to present at Business Unit meeting, Business Unit will circulate via email for comments and agreement
Serious Incident Review Group
IO and AO present investigation reports and action plans for discussion, scrutiny and agreement
Once Agreed: -
Serious Incident
ISA
Governance Department – Serious Incident
Send report and action plan to CCG or VC for review at next CCG SI Review meeting
Governance Department – Internal Investigation
PDF report and send report and action plan to Division as approved document
Governance Department
Once CCG/VC agree with report and action plan, PDF report and send report and action plan to Division as approved document.
Approved document uploaded to Datix
Accountable Officer/ Business Unit
Upload Final Duty of Candour Letter to Datix
Monitor action plan until completed
Accountable Officer/ Business Unit
Present completed action plan at SIG Action Plan meeting
Governance Department
Completed action plan uploaded to Datix
Key: Working Days
Within 1 Day
Within 2 Days
Within 4 Days
Within 10 Days
Within 20 Days
Within 35 Days
Within 45 Days
Within 60 Days
Within 6 Months

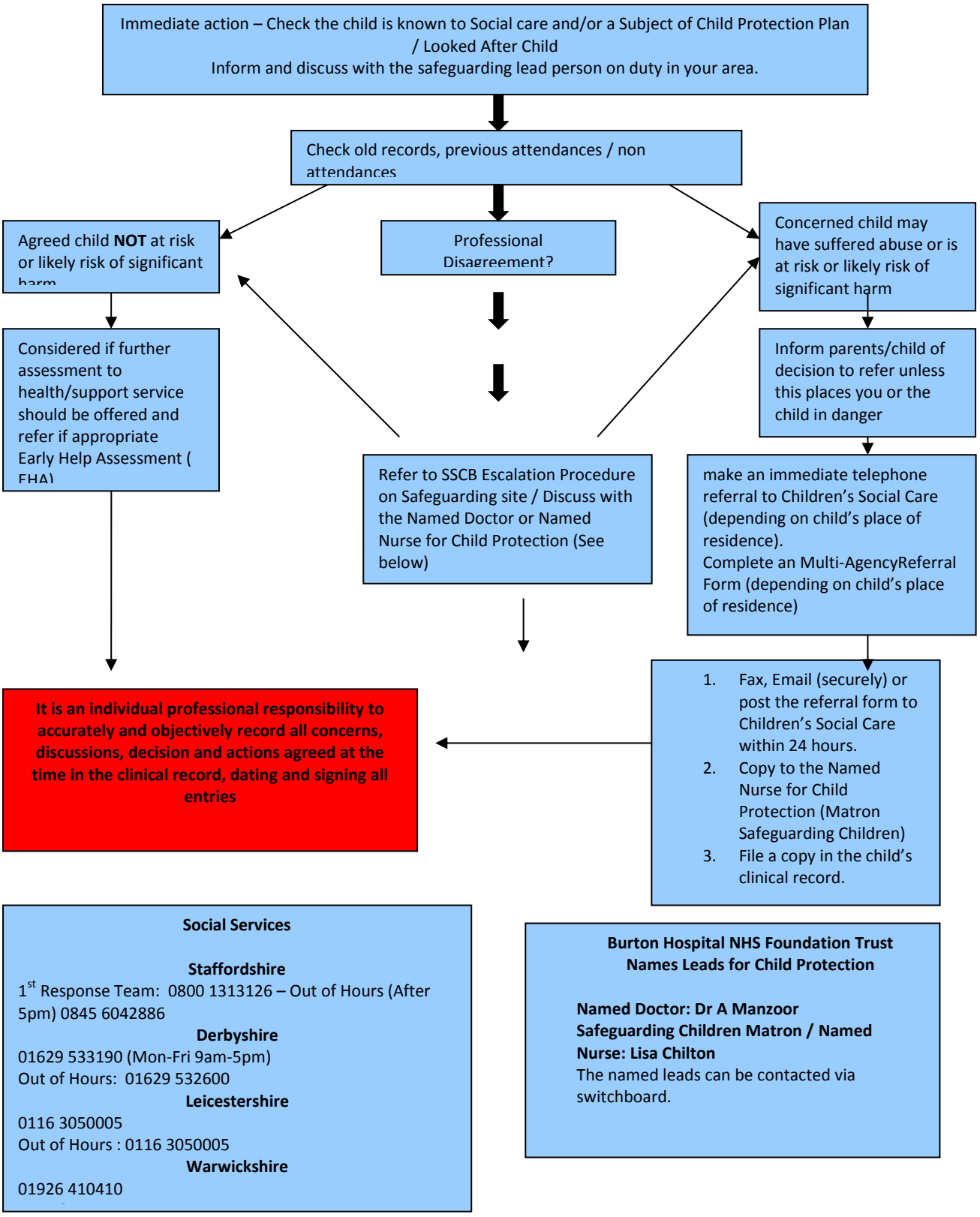
APPENDIX 3

Flow Chart for cases of Suspected Adult Abuse



What to do if you are concerned about Child Abuse Flowchart

All Staff have a duty to safeguard children. It is not your responsibility to prove or disprove any allegations. However, you do have a duty to inform Children's Social Care where there is a concern.


Immediate action – Check the child is known to Social care and/or a Subject of Child Protection Plan / Looked After Child
Inform and discuss with the safeguarding lead person on duty in your area.
Check old records, previous attendances / non attendances
Agreed child NOT at risk or likely risk of significant harm
Professional Disagreement?
Concerned child may have suffered abuse or is at risk or likely risk of significant harm
Considered if further assessment to health/support service should be offered and refer if appropriate Early Help Assessment (EHA)
Inform parents/child of decision to refer unless this places you or the child in danger
Refer to SSCB Escalation Procedure on Safeguarding site / Discuss with the Named Doctor or Named Nurse for Child Protection (See below)
make an immediate telephone referral to Children's Social Care (depending on child's place of residence).
Complete an Multi-AgencyReferral Form (depending on child's place of residence)
1. Fax, Email (securely) or post the referral form to Children's Social Care within 24 hours.
2. Copy to the Named Nurse for Child Protection (Matron Safeguarding Children)
3. File a copy in the child's clinical record.
It is an individual professional responsibility to accurately and objectively record all concerns, discussions, decision and actions agreed at the time in the clinical record, dating and signing all entries
Social Services
Staffordshire
1st Response Team: 0800 1313126 – Out of Hours (After 5pm) 0845 6042886
Derbyshire
01629 533190 (Mon-Fri 9am-5pm)
Out of Hours: 01629 532600
Leicestershire
0116 3050005
Out of Hours : 0116 3050005
Warwickshire
01926 410410
Burton Hospital NHS Foundation Trust
Names Leads for Child Protection
Named Doctor: Dr A Manzoor
Safeguarding Children Matron / Named Nurse: Lisa Chilton
The named leads can be contacted via switchboard.

HEALTHCARE ASSOCIATED INFECTIONS: ROOT CAUSE ANALYSIS

(Local agreement to complete the initial process within 10 working days)
The Chief Nurse is the Lead Director

Root Cause Analysis (RCA) is required in the following instances:

Mandatory
- All cases of MRSA bacteraemia
- All cases of *Clostridium difficile* entered on part 1a,1b or 1c of a death certificate

These are Serious Incidents (SIs) that must be reported to QG&R team for SI reporting to CCG

Local decision
- All other cases of Clostridium difficile

Working Day 1

The IPCT will:
Enter details on the HPA MESS surveillance website

The IPCT will notify:
- DoN/DIPC/CD
- Head Nurse/Matron
- Ward Manager
- Consultant for the patient
- Directorate Manager
- Antibiotic Pharmacist
- QG&R team
- Domestic Services Manager

Working Day 1

QG&R teamwill:
- Complete SI monitoring sheet
- Report on STEIS
- Report to Chief Executive
- Report to CCG
- Enter on incident database
- Enter onto board report

By Working Day 12
QG&R teamwill:
- Update STEIS
- Update the CCG
- Update the Board report

Working Day 1

The Head Nurse will:
- Appoint a matron to lead the investigation

RCA Meeting attendees
- Head Nurse
- Matron
- Ward Manager
- Consultant for the patient
- Operational Support Manager
- Consultant Microbiologist
- Infection Prevention and Control Nurse
- Divisional Quality Governance and Risk Facilitator
- Domestic Services Manager
- Head Nurse Infection Control SSPCT
  For C.diff the Doctor who prescribed the antibiotic

Additional determined by RCA lead:
- Antibiotic Pharmacist
- District Nurse
- CCG Manager

Working Day 2-8

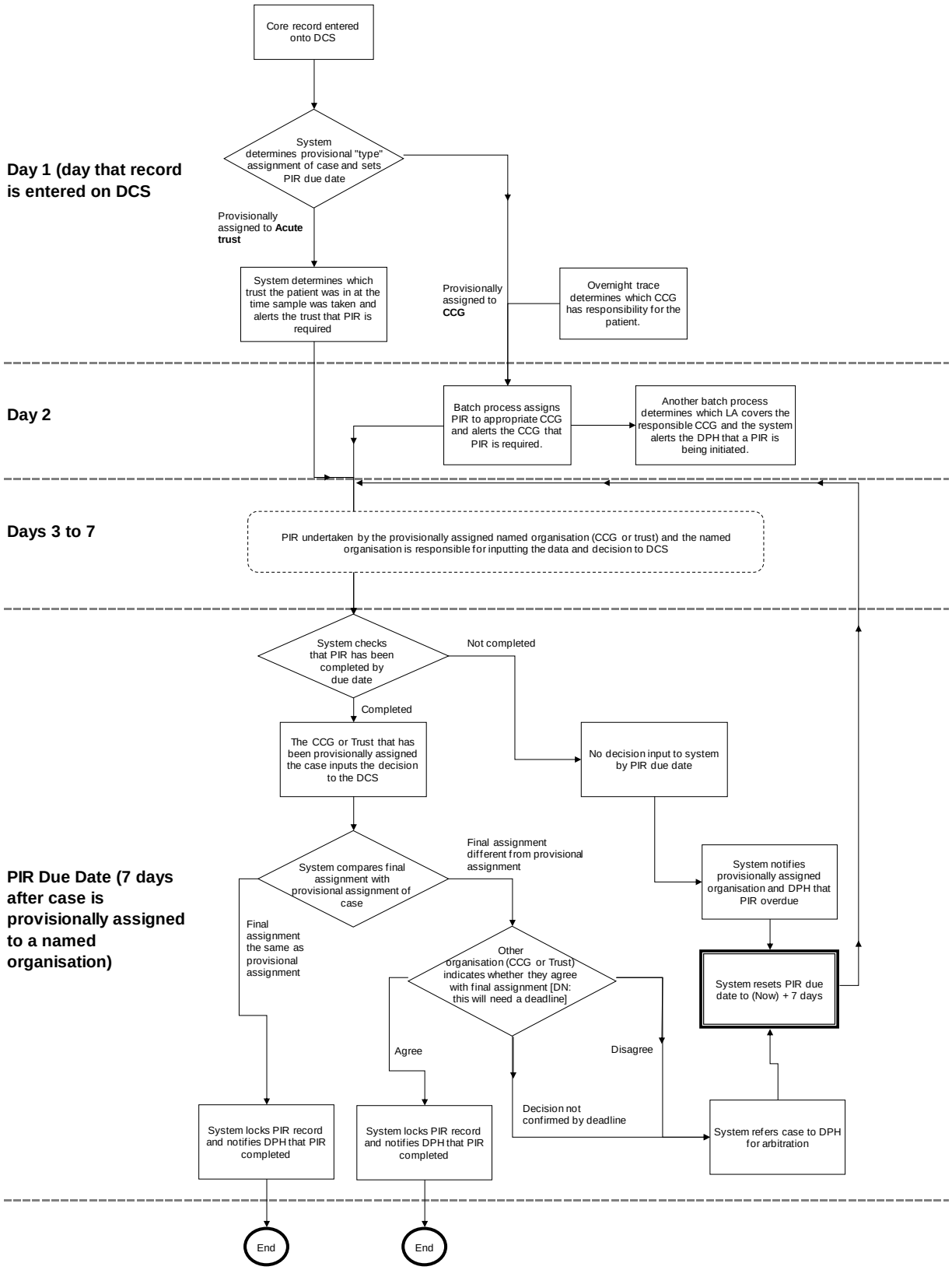
Matron will
- Lead RCA data gathering investigation
- Arrange RCA Meeting
- Ensure that papers are distributed at least 24 hrs before the meeting

By working Day 10

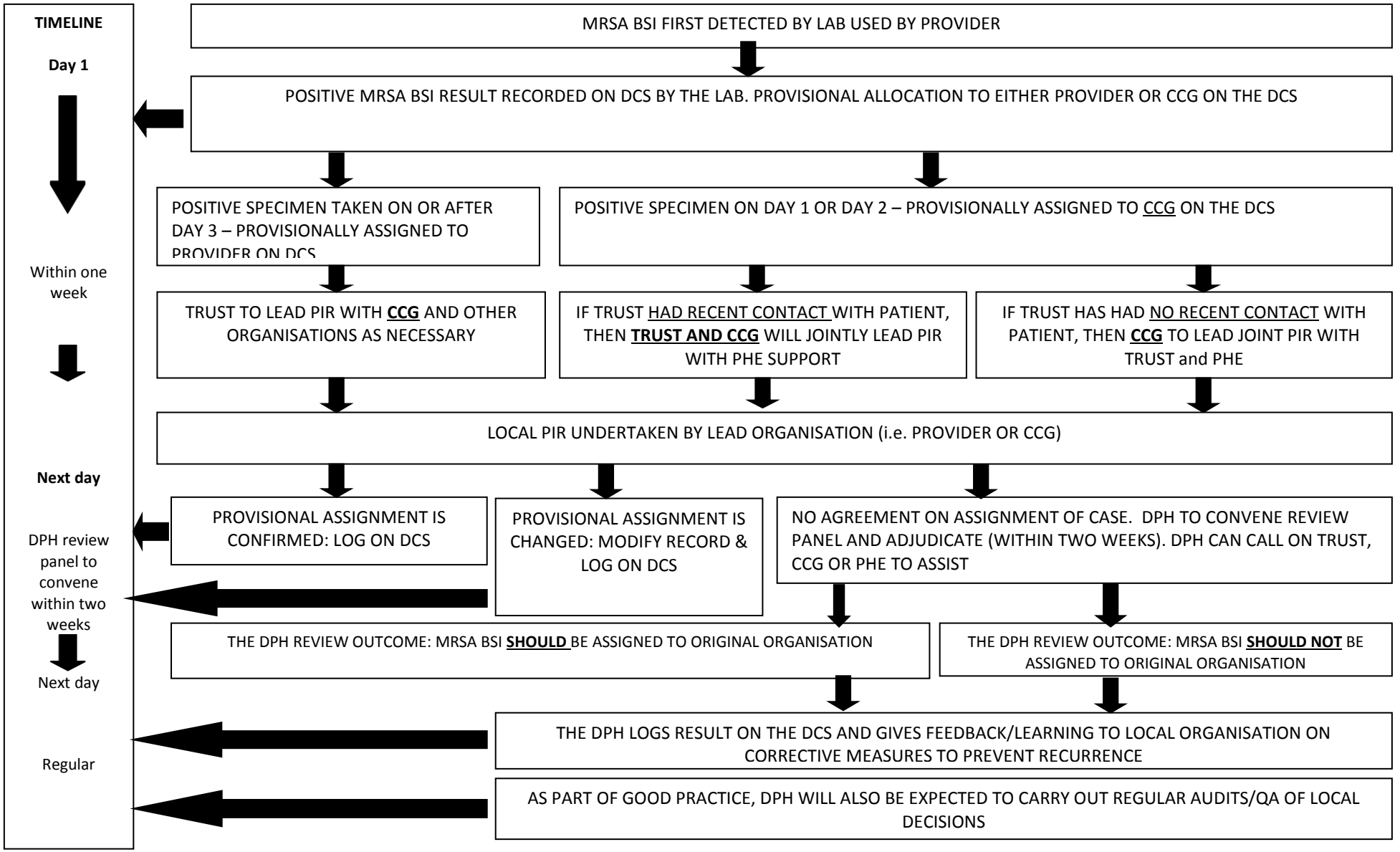
The Head Nurse will:
- Chair the RCA review meeting
- Approve the RCA action plan and ensure that it is initiated
- Liaise closely with QG&R team to ensure that requisite information is provided.
- Report to the Lead Director
- Ensure that the action plan is implemented within 1 month of RCA meeting

The Lead Director will:
- Report to the Trust Board and CCG (via quality meetings)

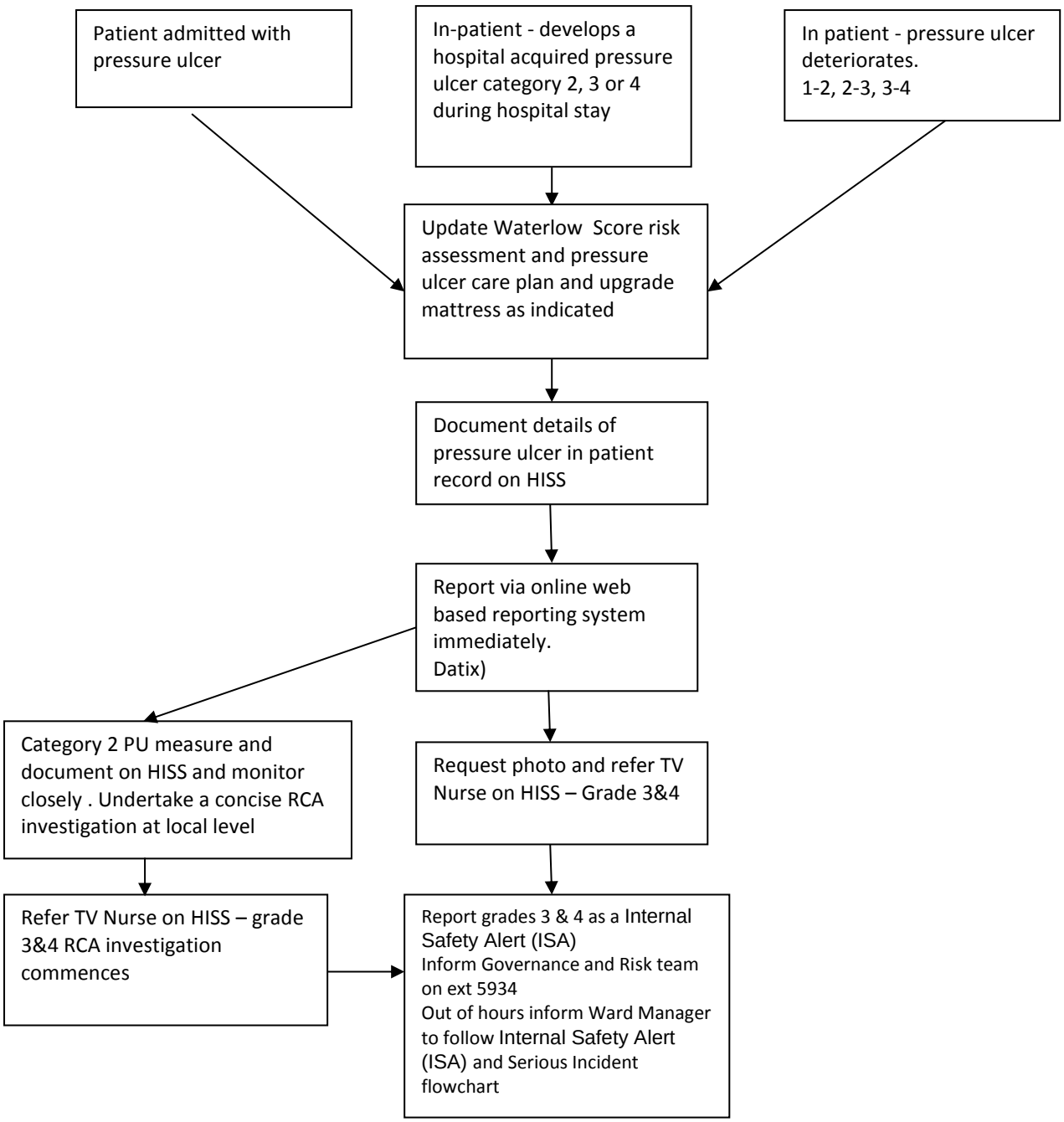
Completing the PIR



MRSA BLOODSTREAM INFECTION (BSI): GENERAL REPORTING ARRANGEMENTS FROM 2013



Process for Notification of Pressure Ulcer (PU) Damage



RISK GRADING

Severity

Choose the most appropriate domain for the identified risk from the left hand side of the table Then work along the columns in same row to assess the severity of the risk on the scale of 1 to 5 to determine the consequence score, which is the number given at the top of the column.

	Consequence score (severity levels) and examples of descriptors				
	1	2	3	4	5
Domains	Negligible	Minor	Moderate	Major	Catastrophic
Impact on the safety of patients, staff or public (physical/psychological harm)	Minimal injury requiring no/minimal intervention or treatment. No time off work	Minor injury or illness, requiring minor intervention Requiring time off work for >3 days Increase in length of hospital stay by 1-3 days	Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4-15 days RIDDOR/agency reportable incident An event which impacts on a small number of patients	Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients
Quality/complaints/audit	Peripheral element of treatment or service suboptimal Informal complaint/inquiry	Overall treatment or service suboptimal Formal complaint (stage 1) Local resolution Single failure to meet internal standards Minor implications for patient safety if unresolved Reduced performance rating if unresolved	Treatment or service has significantly reduced effectiveness Formal complaint (stage 2) complaint Local resolution (with potential to go to independent review) Repeated failure to meet internal standards Major patient safety implications if findings are not acted on	Non-compliance with national standards with significant risk to patients if unresolved Multiple complaints/ independent review Low performance rating Critical report	Totally unacceptable level or quality of treatment/service Gross failure of patient safety if findings not acted on Inquest/ombudsman inquiry Gross failure to meet national standards

Human resources/ organisational development/staffing/ competence	Short-term low staffing level that temporarily reduces service quality (< 1 day)	Low staffing level that reduces the service quality	Late delivery of key objective/ service due to lack of staff Unsafe staffing level or competence (>1 day) Low staff morale Poor staff attendance for mandatory/key training	Uncertain delivery of key objective/service due to lack of staff Unsafe staffing level or competence (>5 days) Loss of key staff Very low staff morale No staff attending mandatory/ key training	Non-delivery of key objective/service due to lack of staff Ongoing unsafe staffing levels or competence Loss of several key staff No staff attending mandatory training /key training on an ongoing basis
Statutory duty/ inspections	No or minimal impact or breech of guidance/ statutory duty	Breech of statutory legislation Reduced performance rating if unresolved	Single breech in statutory duty Challenging external recommendations/ improvement notice	Enforcement action Multiple breeches in statutory duty Improvement notices Low performance rating Critical report	Multiple breeches in statutory duty Prosecution Complete systems change required Zero performance rating Severely critical report
Finance including claims	Small loss Risk of claim remote	Loss of 0.1–0.25 per cent of budget Claim less than £10,000	Loss of 0.25–0.5 per cent of budget Claim(s) between £10,000 and £100,000	Uncertain delivery of key objective/Loss of 0.5–1.0 per cent of budget Claim(s) between £100,000 and £1 million Purchasers failing to pay on time	Non-delivery of key objective/ Loss of >1 per cent of budget Failure to meet specification/ slippage Loss of contract / payment by results Claim(s) >£1 million
Service/business interruption Environmental impact	Loss/interruption of >1 hour Minimal or no impact on the environment	Loss/interruption of >8 hours Minor impact on environment	Loss/interruption of >1 day Moderate impact on environment	Loss/interruption of >1 week Major impact on environment	Permanent loss of service or facility Catastrophic impact on environment

Likelihood

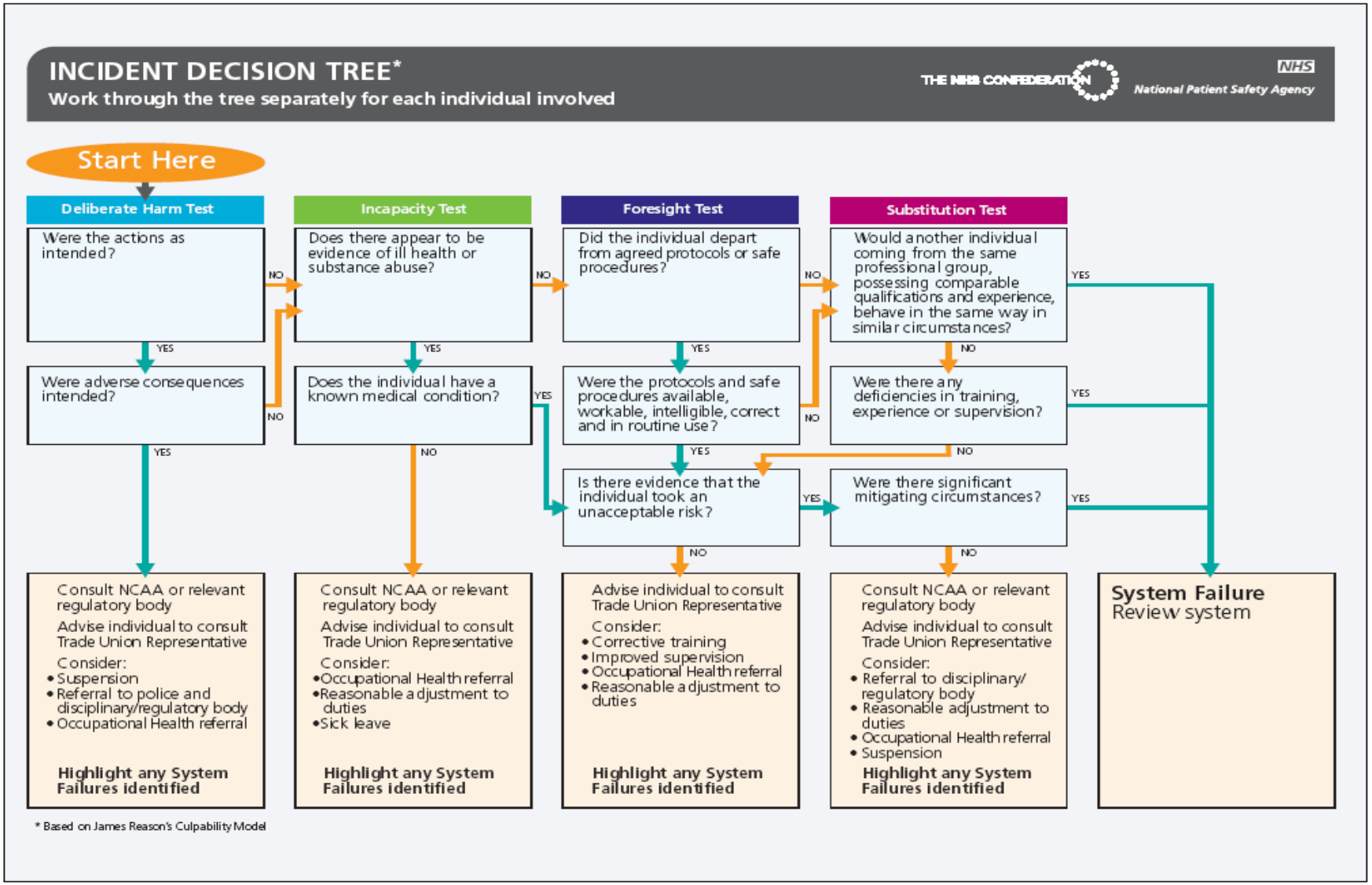
What is the likelihood of the consequence occurring?

Likelihood score	**1**	**2**	**3**	**4**	**5**
Descriptor	**Rare**	**Unlikely**	**Possible**	**Likely**	**Almost certain**
Frequency How often might it/does it happen	This will probably never happen/recur	Do not expect it to happen/recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen/recur but it is not a persisting issue	Will undoubtedly happen/recur,possibly frequently

Risk scoring = consequence x likelihood (C x L)

	Likelihood				
	1	**2**	**3**	**4**	**5**
Consequence	**Rare**	**Unlikely**	**Possible**	**Likely**	**Almost certain**
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

INCIDENT DECISION TREE



Full reporting requirements for provider organisations
Reporting to the regulator (CQC, NHS Improvement)

- Healthcare provider organisations are required to notify the appropriate regulator about incidents that indicate, or may indicate, risks to ongoing compliance with the registration requirements, or that lead, or may lead, to changes in the details about the organisation in the regulator's register.
- Most of the requirements for the CQC, as defined in current regulations guidance, are met by providing incident reports to the NRLS. The NRLS will forward relevant information to the CQC.
- This exception does not apply to independent sector providers or primary care providers registered with CQC. They must report incidents directly to CQC.
- For more information on requirements for reporting to the CQC, see http://www.cqc.org.uk/organisations-we-regulate/registered-services/notifications
- NHS Foundation Trusts are required to report relevant serious incidents requiring investigation to NHS Improvement.
- Incidents must be reported without delay as defined in legislation.

Reporting a serious incident occurring in independent sector healthcare or other provider outside the NHS.

- Independent sector healthcare providers must report any serious incident involving a patient receiving NHS funded care to the commissioning organisation with responsibility for the contract.
- Independent sector healthcare providers should report to the NRLS via the eForm of the NRLS although this is voluntary; CQC must be notified directly of abuse, serious injury and all deaths.
- Independent sector healthcare providers are also responsible for reporting the incident directly to their appropriate regulator.
- NHS CB area teams can, if appropriate, provide access to STEIS for non-NHS providers for reporting purposes as long as those providers are on the NHS N3 network.

Reporting to the Health and Safety Executive (HSE)

- The HSE is responsible for the enforcement of the Health and Safety at Work Act 1974 (HSWA) and ensuring that "risks to people's health and safety from work activities are properly controlled".
- Serious incidents may need to be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR).
- The trigger point for RIDDOR reporting is over seven days' incapacitation (not counting the day on which the accident happened).
- Further information on reporting is available at http://www.hse.gov.uk/riddor/report.htm
- If the serious incident requires joint investigation by the organisation and the HSE and the police, the Memorandum of Understanding should be activated.

Work-related deaths

- Incidents involving work-related deaths (or cases where the victim suffers injuries in such an incident that are so serious that there is a clear indication, according to medical opinion, of a strong likelihood of death) should be managed in accordance with the Protocol on Work Related Deaths.
- In the first instance the incident should be reported within the organisation normal way and to the commissioning organisation.

Reporting to the police

- The police are likely to investigate incidents where there is evidence, or suspicion of, a criminal offence having been committed, e.g. if an incident has arisen from or involves criminal intent, or gross negligence
- In the first instance the incident should be reported within the organisation in the normal way and to the commissioning body.
- Referral to the police should be undertaken by a senior member of staff in the reporting organisation.
- In circumstances of unexpected death or serious harm requiring investigation by the police, the incident should be managed in accordance with the Memorandum of Understanding (currently under review).
- This protocol should be activated when an incident requires investigation by the police and the Health and Safety Executive (HSE) jointly. Reporting to the coroner
- An unexpected death (where natural causes are not suspected) and all deaths of detained patients must be reported to the coroner by the treating clinician.
- This should be done immediately, but recognising that, following an unexpected death, a serious incident may not be identified until the issuing of the coroner's report.

Reporting to Public Health England

PHE Centres:

- Where incidents have the potential to affect population health, the provider should seek advice from the local PHE Centre. Depending on the nature of the incident, other public health organisations such as local authorities may need to be involved.
- Such incidents will include those with a health protection component, such as failures in decontamination.
- The PHECs' health protection staff will provide a risk assessment and advise on appropriate action

National screening programmes

- In the case of a serious incident in a screening programme, the NHS Commissioning Board Area Team Screening and Immunisation Lead is responsible for ensuring that the provider(s) respond to a serious incident in an appropriate and timely manner and take all necessary steps to mitigate any on-going risks . The Regional Quality Assurance Director (for NHS Cancer Screening Programmes) or the Regional Quality Assurance Lead (for NHS Screening Programmes) must be fully involved in the incident management process.
- The provider organisation must report all potential incidents and serious incidents to the Regional QA Director or Regional QA Lead. The Quality Assurance team will undertake initial fact finding with the screening provider and advise on next steps
- Further guidance on handling serious incidents in screening programmes is to be published shortly.

Reporting to NHS Protect

- Where a serious incident occurs to a member of staff resulting from a physical or non-physical assault, there is a requirement to report this to NHS Protect via the Security Incident Reporting System.
- The same reporting requirement relates to incidents involving loss or damage to property and assets of NHS organisations, staff and patients.

Reporting to the Medicines and Healthcare products Regulatory Agency (MHRA)

- Any serious incident involving medication or medical devices should be reported to the MHRA. Details on how to do this are at:

http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

Reporting Health Care Associated Infection (HCAI) serious incidents

- The Health Protection Agency's guidance on *Health Care Associated Infection Operational Guidance and Standards for Health Protection Units* provides information on the steps that should be followed by providers in escalating concerns about the management of a HCAI situation, incident or outbreak and steps for informing commissioners and regulators about concerns. While this will need to be updated to reflect new responsibilities, the principles around recognising incidents, undertaking risk assessments and when to escalate serious HCAI situations / incidents and outbreaks remain valid. The guidance can be found at:

http://www.hpa.org.uk/Publications/InfectiousDiseases/InfectionControl/1207hcaiopguidancestdsforHPUs/

Reporting Serious Adverse Blood Reactions and Incidents (SABRE)

- **The UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive require that serious adverse incidents and serious adverse reactions related to blood and blood components are reported to the MHRA, the UK Competent Authority for blood safety.**
- **This information is vital to the work that the Serious Hazards of Transfusion (SHOT) uses to compile its reports. Further details on reporting can be found at:**

http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Blood/index.htm

Caldicott, data protection and information governance

- When reporting serious incidents, providers must comply with Caldicott, data protection and information governance requirements.
- They should not refer to individuals by name or give other identifiable information, and should “restrict access to patient information within each organisation by enforcing strict need to know principles”.
- In any circumstance where it may be necessary to identify an individual, the serious incident lead in the provider organisation must contact the senior member of the commissioner or local authority to discuss the incident and provide more detailed information.