Incident Reporting and Management Policy

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Table of contents

INCIDENT REPORTING POLICY

1. RATIONALE

The effective reporting and management of incidents is a key component of Yeovil District Hospital NHS Foundation Trust's (the Trust) governance arrangements; and a fundamental mechanism for managing risk and delivering high quality, safe patient care and supporting the health, safety and welling of staff, contractors and visitors to the Trust.

This policy works in conjunction with the NHS England's Serious Incident Framework 2015.

2. AIM

The Trust operates an open, fair and 'blame-free' culture in relation to reporting incidents and near misses. The Trust encourages the reporting of all incidents, including near misses, as an opportunity to learn for the benefit of patients, staff and visitors.

The aim of the Incident Reporting and Management policy is to:

Set out the arrangements and responsibilities for reporting incidents and carrying out investigations;

- Enable the Trust to analyse incident trends, root causes and develop appropriate action plans to eliminate or minimise the risk harm to patients, staff and visitors; and
- Set out the arrangements for reporting externally, including the 'Duty of Candour'.

3. APPLICABILITY

This policy applies to all members of staff in the Trust, including volunteers, and contractors.

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

- NHS England Serious Incident Framework
- Being Open and Duty of Candour Policy
- Complaints and Concerns Management policy
- Safeguarding Adults Policy
- Child Protection Policy
- Raising Concerns (Whistle Blowing) Policy
- Capability Policy
- Disciplinary Policy
- Health and Safety Policy
- Medical Devices Management Policy
- Security policy

Staff should be aware that there may be clearly defined occasions where further action will need to be taken, namely where there has been evidence of a breach of the law, professional misconduct or repetitious incidents caused by negligence. Failure to follow this policy by staff may result in action under either the Disciplinary or Capability policies, or other relevant trust policies.

4. DEFINITIONS

- **Accident**; an unplanned and uncontrolled event that has led to or could have caused injury, ill health, harm to persons, damage to equipment or loss. Accidents can relate to:
    - **Staff accident**; e.g. where staff have sustained injuries from an incident in the workplace (slip, needle stick injury etc)
    - **Accidents to patients and visitors**; where patients and/or visitors have sustained injuries from an incident as a result of actions, omissions or whilst under the care of employees, or one health premises (slips, trips and falls)
- **Adverse event**; an incidents that lead to harm or failure to function.
- **Candour**; any patient harmed by the provision of healthcare service is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about.
- **Clinical incident**; an occurrence, procedure or intervention, which has given rise to actual injury, or to an unexpected or unwanted effect. Examples of clinical incidents include:
    - **Medication error**; e.g. incorrect drug, incorrect dosage through unfamiliar drug label, a drug after its expiry date and an adverse reaction to a drug.
    - **Delay in treatment**; e.g. withholding of treatment without good reason or undue delay in receiving treatment.
    - Where the action or delay in providing care and treatment by the clinical staff contributes to the deterioration of the patients medical condition.
    - **Inappropriate discharge**; e.g. to or from primary care.
- **Equipment failures and deficits**; where operational equipment is missing or it fails during testing or use (e.g. wheelchair not fit for purpose, defibrillator, not charging, and failure of oxygen supply)
- **Fire incident**; any incident involving a fire, or any incident where the fire alarm sounds.
- **Harm**; injury (physical or psychological), disease, suffering, disability or death. Where a patient is concerned harm can be considered unexpected if it is not related to the original cause of the patient's illness or underlying condition or treatment.
- **Loss**; financial loss, or loss of data/information.
- **Near miss**; those incidents that **did not** lead to harm or loss.
- **Openness**; enabling concerns and complaints to be raised freely without fear and questions asked to be answered.
- **Patient safety incident**; any unintended or unexpected incident that could have led, or did lead, to harm for one or more patients.
- **RIDDOR**; Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995.
- **Serious incident**; see section 7.1
- **Security incident**; any incident where a breach or lapse of security is the primary factor (e.g. missing drugs)

- **STEIS;** Strategic Executive Information System, NHS England's web-based serious incident management system
- **Violence and abuse**; where any person is subjected to the threat of, or actual, violence and/or verbal abuse.
- **Work related ill health**; illness directly work related (e.g. latex allergy).

5. RESPONSIBILITIES

5.1 The **Chief Executive and Board of Directors** have overall responsibility for the implementation of this policy and provisions. They are responsible for ensuring that an open culture of reporting is promoted across the Trust and that there are systems in place for shared learning and delivering service improvement.

5.2 The **Director of Nursing and Clinical Governance** is responsible for ensuring governance arrangements are in place to provide the leadership and support necessary to manage the provisions of this policy. Management of the incident reporting process is delegated to the Associate Director of Patient Safety and Quality.

5.3 The **Associate Director of Patient Safety and Quality, or Deputy,** will ensure incident reporting systems are maintained and processes are supported and monitored including:

- Advising on the level of investigation required and commissioning investigations
- Ensuring effective external reporting mechanisms are in place and that they are reported in accordance with national guidance.
- Providing access to training for incident reporting and investigation
- Reviewing serious investigation reports for accuracy
- Ensuring that action plans resulting from investigations are monitored and followed through
- Supporting the Trust with incident reporting data, including the identification of trends for risk reduction measures
- Overseeing the Trust's Patient Safety Improvement Programme
- Ensuring that 'Being Open' and 'Duty of Candour' processes are followed when a patient safety incident occurs
- Ensuring that any concerns about professional performance or competency are reported to Human Resources in the event that individual staff are identified as at fault following a serious incident investigation.
- To attend meetings of the Serious Incident Review Group.

5.4 The **Strategic Business Unit (SBU) Senior Team**, **Associate Medical Director** and **Associate Directors of Nursing** are responsible for:

- Promoting openness within their teams around reporting incidents and providing feedback to patients
- Reviewing incident data to identify trends and agree risk reduction measures within the SBU
- Ensuring that nominated investigators are appropriately trained, and that investigations are carried out within the required time frames

- Monitoring progress with action plans resulting from incident investigations, and ensuring adequate resource for their implementation where required
- Ensuring disciplinary processes are followed in the event of an individual(s) being identified as at fault following a serious incident investigations, in line with HR procedures

5.5 **Managers** who directly manage services (including Ward Sisters, Matrons and Departmental leads) are responsible for:

- Ensuring that they have received the relevant training, and have the appropriate access set up so that they can manage incidents for their area
- Reviewing all incidents for their service area/department and validating the actual impact/severity
- Completing the 'managers action' section of the incident form to include any actions taken or planned
- Providing support to staff who report incidents and timely feedback once they have been investigated and signed off
- Nominating a deputy to respond to incidents when away
- Ensuring that Being Open and Duty of Candour processes are followed at ward or department level.
- Leading / overseeing investigations relating to their area of responsibility

5.6 The **Patient Experience Manager**, working with the Governance Department, is responsible for:

- Contacting the patient and/or their family when the Duty of Candour is triggered
- Writing formally to the patient/family providing an apology and information on the investigation process.
- Act as a liaison between the Trust and the patient/family throughout the investigation process, including arranging a conciliation meeting where required.
- Ensuring meetings with patients/families/carers are carried out and supported appropriately
- To attend meetings of the Serious Incident Review Group

5.7 The **Risk and Safety Manager** is responsible for

- Ensuring effective external reporting mechanisms are in place and that they are reported in accordance with national guidance.
- Oversee the operational management of the incident reporting system
- Providing access to training for incident reporting and investigation
- Reviewing serious investigation reports for accuracy
- Supporting the Trust with incident reporting data, including the identification of trends for risk reduction measures
- Leading the Trust's Patient Safety Improvement Programme
- Ensuring that 'Being Open' and 'Duty of Candour' processes are followed when a patient safety incident occurs

5.8 The nominated **Investigating Officer** is responsible for

- Undertaking the appropriate level of local investigation and root cause analysis as commissioned by the Associate Director of Patient Safety and Quality.
- Communicating with internal and external stakeholders as appropriate to assist in the investigation process and to ensure lessons are learnt.
- Ensuring staff and any patients or their relative/carer affected are invited to contribute to the investigation process and are notified of the outcome and actions taken to prevent re-occurrence. (Refer to the Policy and Procedure for Being Open)
- In consultation with the managers (ward sisters, matrons, heads of department), relevant areas, make recommendations for actions to prevent reoccurrence, to include the preparation of an action plan and/or improvement strategy.
- Provide a copy of the final investigation report to the Clinical Governance Department for quality assurance processes, including forwarding the report to the relevant internal and external stakeholders.
- Ensuring they are appropriately trained to undertake on root cause analysis (see section 10)

5.9 The **Systems Administrator (Risk and Safety)**, is accountable to the Trust's Risk and Safety Manager and acts as the incident liaison officer. The are responsible for:

- Maintaining the operational management of the incident reporting system
- Checking incident reports as soon as reasonably practical, including the grading of risk and actual impact, and to identify if further investigation or actions are required
- Ensuring that incident reports are fully anonymised before being uploaded to the National Reporting and Learning System (NRLS) or Security Incident Reporting System (SIRS)
- Undertaking the monthly upload of incident data to the NRLS and SIRS
- Logging all externally reportable incidents to STEIS
- Uploading RIDDOR reportable incidents to Health and Safety Executive (HSE) as required and within the relevant timeframes.
- Ensuring the web notifications within the incident reporting system reflect the organisational structures of the Trust
- Maintaining the Trust's register of serious incidents
- Scanning all records and notes into the appropriate investigation folders
- Providing the administration support to the Serious Incident Review Group.
- Ensuring that the nominated investigating officer is provided with the current templates and information required to commence an investigation.
- Provide training and ongoing support on the use of the Safeguard incident reporting system

5.10 The **SBU Quality Improvement (QI) Leads** will work with the relevant SBU senior team and managers and are responsible for:

- Monitoring levels of incident reporting, identifying themes and trends

- Assisting in the formulation of action plans and ensuring that they are included in the relevant work plan.
- Ensuring that overdue action plans are brought to the attention of the SBU and reported through the appropriate governance meetings
- Working with the Systems Administrator (Risk and Safety) to maintain the Trust's serious incident register
- Quality assuring investigation reports prior to them being reviewed at the Serious Incident Review Group and Patient Safety Steering Group
- Providing support to nominated investigating officers as required.

5.11 The **Serious Incident Review Group** reports to the Patient Safety Steering Group and is responsible for:

- Providing an oversight of the process for investigating serious incidents, ensuring that investigations are completed within the relevant timescale.
- Quality assuring completed serious incident investigation reports
- Ensuring that the Duty of Candour is applied as appropriate.

5.12 The **Patient Safety Steering Group** reports to the Clinical Governance Assurance Committee, which is a sub-committee of the Board of Directors, and is responsible for:

- Ensuring that key themes and lessons learned from serious incidents are identified and shared across the Trust for continuous quality improvement.
- Monitoring the incident reporting process to ensure that these are functioning in accordance with regulatory requirements and that staff are appropriately engaged with the process.
- Monitor action plans against the requirements for Monitor and the Care Quality Commission whilst ensuring compliance with Patient Safety standards.

5.13 All **Staff** are responsible for:

- Ensuring that they have received appropriate training on how to access and report incidents using the Trust's web-based reporting system
- Reporting incidents as soon as they are identified
- Ensuring incidents that cause harm are notified to their manager, or higher, at the earliest opportunity
- Seeking support from their manager and/or Occupational Health if they are affected by an incident
- Raising concerns if they witness or feel that patient care is being adversely affected

6. WHEN AN INCIDENT OCCURS

6.1 Immediate action

Annex A provides a flow chart of the incident reporting process.

The person identifying the incident should take immediate action to ensure the safety of patient(s), other service users and staff and then report the incident to the person in charge of that area. For areas with no local manager (e.g. in corridors or car parks) the

appropriate facilities, or housekeeping and domestic team, should be informed if action needs to be taken.

When the incident involves a patient, details of the incident should also be recorded in the medical and/or nursing notes with appropriate follow up as necessary.

6.2 Reporting an incident

6.2.1 Incident reporting system

All incidents, including near misses, must be reported on the Trust's web-based incident reporting system, Safeguard, accessed via the intranet (link on the yCloud homepage). They should be reported at the earliest opportunity, following an incident occurring, or the incident being identified.

If an incident is identified after the event, the incident report should be completed by the person who identified it. All applicable fields of the incident report form should be completed including details of any witnesses so that they can be interviewed if an investigation is required.

6.2.2 Impact of the incident

The incident report includes questions to help identify the **actual impact** (level of 'harm' or 'loss') of the incident, in line with the risk matrix shown at Annex B. When reporting a patient safety incident the actual impact indicates the seriousness of the incident and will help inform the level of investigation required.

6.2.3 Manager Action

Safeguard automatically notifies relevant managers and other key Trust staff. Managers must log in to the system and ensure the following:

- Confirm the details of the incident and ensure that the risk assessment, and the actual impact, scoring is appropriate.
- Advise senior managers if the incident is deemed serious.
- Feed back to the individual who submitted the report of any actions taken as a result and provide support accordingly.
- Complete and update the incident report as soon as possible, within a maximum of 30 days of the incident being reported, to include:
    - The underlying reasons for the incident occurring; and
    - Actions taken to prevent recurrence.

6.2.4 National Reporting and Learning System (NRLS)

All patient safety incidents (including serious patient safety incidents as described in section 7) are uploaded to the NRLS each month by the Systems Administrator (Risk and Safety). The system enables patient safety incident reports to be submitted to a national database, this data is then analysed centrally to identify hazards, risks and opportunities to improve patient safety nationally.

7. IDENTIFYING AND REPORTING SERIOUS INCIDENTS

7.1 Identifying a serious incidents

As defined by NHS England's Serious Incident Framework, serious incidents in the NHS include:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
    - Unexpected or avoidable death of one or more people. This includes
        - suicide/self-inflicted death; and
        - homicide by a person in receipt of mental health care within the recent past.
    - Unexpected or avoidable injury to one or more people that has resulted in serious harm;
    - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
        - the death of the service user; or
        - serious harm;
    - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
        - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
        - where abuse occurred during the provision of NHS-funded care.
        - This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident (see Part One; sections 1.3 and 1.5 for further information).
- 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 (by provider, commissioner or relevant agency)

- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation
- Incidents which activate the NHS Trust or Commissioner Major Incident Plan:
- Incidents which will be of significant public concern:
- Incidents which will give rise to significant media interest or will be of significance to other agencies such as the police or other external agencies:

7.2 Reporting a serious incident

7.2.1 Internal reporting arrangements

All incidents, including serious incidents (as described in 7.1), must be reported on the Trust's web-based reporting system, Safeguard, as outlined in section 6.

When a serious incident has occurred, then the notification process outlined in Annex C must be followed (this includes arrangements out-of-hours).

7.2.2 External reporting arrangements

The Trust must report serious incidents to the Somerset CCG no later than two working days after a serious incident is identified. Serious patient safety incidents must also be reported on the NHS serious incident management system (STEIS) within two working days of the incident being identified. The Clinical Governance Team are responsible for ensuring that all incidents fitting the criteria are reported as necessary within the timescale.

Other regulatory, statutory, advisory and professional bodies should be informed about serious incidents depending on the nature and circumstances of the incident. This should be discussed and agreed with the Clinical Governance Team (Associate Director of Patient Safety & Quality). Serious incident reports must clearly state that relevant bodies have been informed.

7.3 Immediate action following a serious incident

A senior manager or clinician should be identified by the Associate Director of Quality and Patient Safety, or Deputy, to undertake the following:

- Arrange for any immediate actions required to ensure the safety of the patient(s), other service users and staff.
- Obtain all relevant physical, scientific and documentary evidence, and make sure it is secure and preserved. Initial actions of local managers in the collection and retention of information are important for the overall integrity of the investigation process.
- Identify witnesses, including staff, and other service users, to ensure they receive effective support.
- Identify an appropriate specialist/clinician to conduct an initial incident review (72-hour review) to confirm whether a serious incident has occurred and if applicable, the level of investigation required and to outline immediate action taken (including where other organisations/partners have been informed)
- Ensure commissioners and other relevant parties (for example, police, Safeguarding Professionals, the Information Commissioner's Office) are informed at the earliest opportunity and within two working days of a serious incident being identified.

- Agree who will make the initial contact with those involved, or their family/carer(s). Where an individual(s) has been harmed by the actions of a patient, particular thought should be given to who is best placed to contact the victim and/or their family. Where necessary the Trust must contact the police and agree with them who will make the initial contact with the victim(s), their family/carer(s) and/or the perpetrator's family. Those involved should have a single point of contact within the Trust, such as the Patient Experience Manager.
- Arrange appropriate meeting(s) with key stakeholders, including patients/victims and their families/carers as required.

7.4 Reporting cases of restraint

An incident form should be submitted in any case where restraint is used for any reason. If the restraint results in harm, including low harm, a separate incident form should be submitted which includes the following information:

- The type or types of restraint used
- The duration of each type of restraint
- The events leading up to the restraint being used
- Details about the harm to the patient
- Detail about what physical observations were undertaken and recorded during the restraint.

7.5 Reporting pressure damage

Please refer to Annex G and H.

7.6 Safeguarding incidents

Please refer to Annex I.

7.7 Surgical site infections

Since October 2007 the Trust has participated in the Public Health England (PHE) Surgical Site Infection Surveillance (SSIS) programme.

All patients undergoing the following surgical procedures are flagged and reviewed by the Infection Control Team at defined stages post-operatively:

- Total knee replacement
- Total hip replacement
- Abdominal hysterectomy
- Repair of neck of femur and reduction of long bone fracture

The data on incidence of surgical site infections is submitted to the PHE, who produce quarterly reports which benchmark the Trust against other participating hospitals in the programme. Post Infection review's (PIR's) are conducted on all SSI's and these are then presented and discussed at the SSISS working group and the Trust's Infection Prevention and Control Committee.

SSI reports are generated quarterly for discussion at Senior Microbiologist and Infection Control Leads (SMICL), the Strategic Infection and Prevention and Control (SIPAC) and Patient Safety Steering Group (PSSG) meetings.

7.8 **Managing Safety Incidents in National Screening Programmes** –

New guidance has been developed in collaboration by the NHS screening programmes and NHS England. The full guidance can be accessed at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/472611/Managing_Safety_Incidents_in_National_Screening_Programmes_gateway_291015.pdf. This guidance is to be used to support the reporting, investigation and management of incidents in screening programmes. It incorporates a process for assessing whether a quality concern is a screening safety incident or a serious incident.

8. INVESTIGATING SERIOUS INCIDENTS

Appendix 1 provides NHS England's overview of the incident management process.

8.1 Levels of investigation

The nature, severity and complexity of serious incidents vary on a case-by-case basis and therefore the level of response should be depend on and proportion to the circumstances of each specific incident. The appropriate level of investigation should be informed by an initial review (see 8.2). There are three levels of investigation as shown in the table below:

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

	size of the organisation or the capacity / capability of the available individuals and / or number of organisations involved		being investigated	

8.2 **Initial review (72 hour report)**

An initial review (characteristically termed a '72 hour review') should be undertaken for those incidents that meet the criteria listed in 7.1, and uploaded onto STEIS. This should be completed within three working days of the incident being identified. The aim of the initial review is to:

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

The information submitted as part of the initial review should be reviewed by all appropriate stakeholders and the Director of Patient Safety and Quality in order to inform the level of investigation required.

8.3 **Investigation process**

When a serious incident has been identified the Associate Director of Patient Safety and Quality will nominate an investigating officer(s); this will be responsible for ensuring that an appropriate serious incident team is established. It is the responsibility of all team members to keep the Trust fully briefed about the incident and actions being taken. The investigation team is also responsible for identifying valuable/safety-critical learning to be shared at any stage of the investigation process. The team should not wait until completion of the investigation to highlight system weaknesses/ share valuable learning which may prevent future harm.

The nominated investigating officer/team should have:

- Knowledge of what constitutes an effective systems investigation process, and the skills/ competencies to lead and deliver this;
- Skills/ competencies in effective report writing and document formulation;
- Expertise in facilitating patient/family involvement
- Understanding of the specialty involved – this often requires representation from more than one professional group to ensure investigation balance and credible;
- Responsibility for administration and documentation (or for there to be adequate administrative and IT support);
- Access to appropriate legal and/or information governance support where appropriate;
- Access to competent proof-reading services where required; and
- Appropriate links/mechanisms to share lesson locally and nationally during the investigation as required.

8.4 **Investigation report and action plan**

Serious incident investigation reports must be shared with key interested stakeholders including patients, victims and their families (see section 9 regarding the Duty of Candour). It is recommended that reports are drafted on the basis that they may become public, so issues concerning anonymity and consent for disclosure of personal information are important and should be considered at an early stage in the investigation process. Those investigating serious incidents can seek advice from the Trust's Caldicott Guardian if guidance is needed about the disclosure of patient identifiable information.

8.4.1 **Final report**

Report templates will be provided by the Clinical Governance Department once an investigating officer has been identified.

The investigation concludes with an investigation report and action plan. This needs to be written as soon as possible and in a way that is accessible and understandable to all readers.

The report should:

- Be simple and easy to read;
- Disclose only relevant confidential personal information for which consent has been obtained, or if patient confidentiality should be overridden in the public interest. This should however be considered by the Caldicott Guardian and where required confirmed by legal advice;
- Include evidence and details of the methodology used for an investigation (for example timelines/cause and effect charts, brainstorming/brain writing, nominal group technique, use of a contributory factor Framework and fishbone diagrams, five whys and barrier analysis);
- Identify root causes and recommendations;
- Ensure that conclusions are evidenced and reasoned, and that recommendations are implementable (see section 8.5.2 below);
- Include a description of how patients/victims and families have been engaged in the process;
- Include a description of the support provided to patients/victims/families and staff following the incident.

8.4.2 **Action plan**

A SMART approach to action planning is essential. That is, the actions should be: Specific, Measurable, Attainable, Relevant and Time-bound. To ensure that the most effective actions/solutions are taken forward, it is recommended that an option appraisal of the potential actions/solutions is undertaken before the final action plan is developed and agreed.

- Action plans must be formulated by those who have responsibility for implementation, delivery and financial aspects of any actions;
- Every recommendation must have a clearly articulated action that follows logically from the findings of the investigation;
- Actions should be designed and targeted to significantly reduce the risk of recurrence of the incident. It must target the weaknesses in the system (i.e. the

'root causes' /most significant influencing factors) which resulted in the lapses/acts/omissions in care and treatment identified as causing or contributing towards the incident;

- A responsible person must be identified for implementation of each action point;
- There are clear deadlines for completion of actions;
- There must be a description of the form of evidence that will be available to confirm completion and also to demonstrate the impact implementation has had on reducing the risk of recurrence;
- All actions identified should be included on the most appropriate work plan for monitoring.
- Actions that are overdue must be discussed by the relevant SBU.

8.4.3 **Quality assurance process**

All investigation reports must be reviewed and agreed by those involved to ensure they are complete and accurate before they are submitted for internal review.

Completed investigation reports will be reviewed by the relevant SBU's Quality Improvement Lead. The QI Leads will ensure that all reports are fit for purpose, appropriately anonymised and that actions that have been agreed with the staff responsible for taking them forward.

Completed reports will be discussed at the Serious Incident Review Group where the reports, learning and action plans will be discussed and approved prior to ratification at the Patient Safety Steering Group.

The investigating officer(s) and Clinical Governance Team are responsible for the security of documents and information and must have due regard to Caldicott principles on patient confidentially and Data Protection Act requirements.

9. DUTY OF CANDOUR & SUPPORTING THOSE INVOLVED

Duty of candour (CQC regulation 20) should be applied in all serious incidents where harm is caused (moderate harm, severe harm, death and prolonged psychological harm). It is a statutory requirement that has been introduced to ensure health care providers operate in a more open and transparent way when certain incidents occur in relation to the care and treatment provided to people using the service.

Annex D outlines the process for Duty of Candour, for further information please refer to the Being Open and Duty of Candour Policy

9.1 **Involving patients, victims and their families/carers**

Please refer to the Being Open and Duty of Candour Policy.

9.2 **Supporting Staff**

It is important to recognise that serious incidents can have a significant impact on the staff involved or who may have witnessed an incident. Like victims and families they will want to know what happened and why and what can be done to prevent the incident happening again.

Staff involved in to the investigation process should have the opportunity to access professional advice from their relevant professional body or union, staff counselling services and occupational health services. They should also be provided with

information about the stages of the investigation and how they will be expected to contribute to the process.

It must be made clear to staff involved that investigation process is separate to any other legal and/or disciplinary process. The Trust advocates justifiable accountability but there is zero tolerance for inappropriate blame, those involved must not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration by virtue of involvement in the investigation process.

10. DISCIPLINARY AND CAPABILITY PROCESS

The incident decision tree (Appendix 2) should be used to promote fair and consistent treatment of staff. In the very rare circumstances where a member of staff has committed a criminal or malicious act, the member(s) of staff should be advised at an early stage to enable them to obtain separate legal advice and/or representation.

In cases where individuals have been identified as making serious mistakes, or where their competence may be in question, a decision must be made about whether they are able to remain in their current role for the safety of patients and others. In such cases it may be appropriate to instigate the Disciplinary or Capability Policy. The senior SBU team must make a decision, with guidance from the Associate Director of Patient Safety and Quality and Human Resources.

The decision to report individuals to their governing bodies, such as the General Medical Council (GMC) or Nursing and Midwifery Council (NMC), will be taken through the Medical Director or the Director of Nursing.

Any decisions must be communicated to the individual and their line manager, in line with the Disciplinary or Capability Policy, and documented on the staff member's personnel file.

11. STAFF RAISING CONCERNS

A member of staff who wishes to report concerns in person, or outside the incident reporting system, should follow the guidance provided in the Trust's Raising Concerns (Whistle Blowing) Policy; advice is also available on the Trust's intranet site.

12. ANALYSIS AND REVIEW

The Governance Department will produce quantitative reports on a quarterly basis as part of the Trusts Quality Report. The report will detail the number of incidents reported on a range of patient safety aspects including all incidents by risk category and by SBU/Clinical Business Unit (CBU). Data from the NRLS reports will be used to support this information on levels of reporting against other acute trusts.

The number of internally and externally reported investigations will also be reported.

The Quality Improvement Leads will also provide SBU level data as required.

Incidents are reviewed at the Patient Safety Steering Group, Governance Assurance Committee and SBU/CBU meetings as part of the governance agenda. Specific incident categories will be reviewed at relevant patient safety meetings (such as falls and pressure ulcers) or task and finish groups as appropriate.

Areas of focus will support the Trusts activities to reduce risk, areas of improvement and progress will be monitored through the Trusts Patient Safety Improvement Programme.

All incident investigations completed, with lessons learned and actions taken may be considered for presentation at the quarterly Trustwide Rolling Governance meetings to

allow cross-organisation learning; this may include externally reported incidents that have been shared across healthcare organisations.

13. TRAINING REQUIREMENTS

Incident reporting and investigation training will be carried out in line with the Training Needs Analysis (TNA). The training available includes:

- Induction training for all new staff
- Managers training, 'How to Manage Risk'
- Ad hoc online e-reporting system managers attend training on the Safeguard incident reporting system.
- Root Cause Analysis (RCA) training for nominated staff.
- NHS England provide tools for completing incident investigations (http://www.england.nhs.uk/ourwork/patientsafety/root-cause/)

Details of all training on investigation processes and root cause analysis to assist in implementing this policy can be accessed via the Clinical Governance Department.

14. IMPLEMENTATION, MONITORING AND EVALUATION

Responsibility for implementation, monitoring and evaluation is identified in the Trust's Policy on Procedural Documents. An equality impact has been carried out to ensure the policy is fair and does not discriminate any staff groups. A completed Equality Impact Assessment can be found at Annex J.

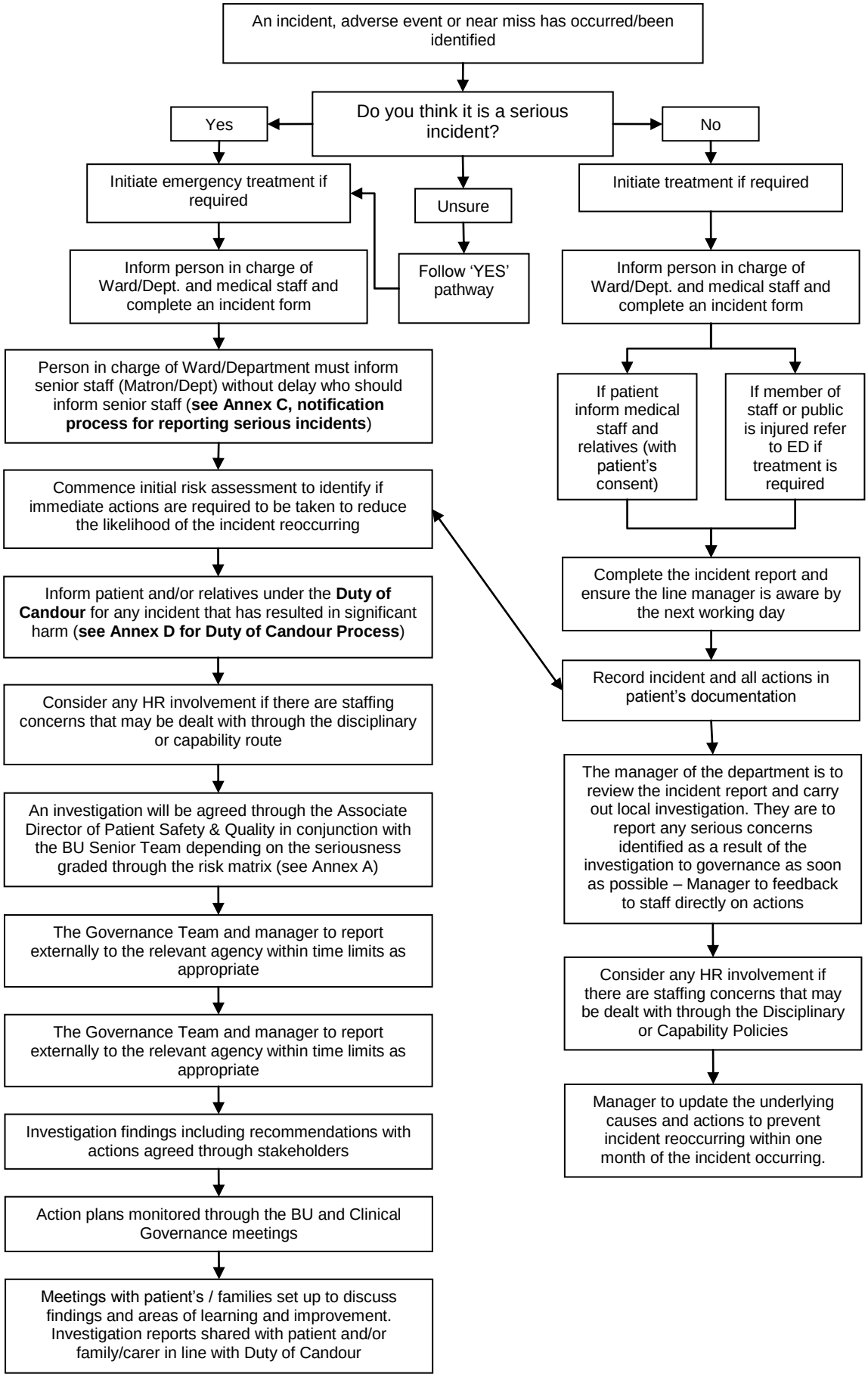
14.1 Internal key performance indicators

- 72 hour report to be completed for all STEIS reportable incidents.
- Initial investigation reports to be completed within 14 days
- Full RCA report to be submitted to the Clinical Governance Department within 45 days, in order to achieve the national requirement of submission within 60 days.

15. FURTHER READING

- More information on the Duty of Candour is available on https://www.gov.uk/government/consultations/statutory-duty-of-candour-for-health-and-adult-social-care-providers
- NHS England Serious Incident Framework http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf

ANNEX A – Patient Safety Incident Reporting Flowchart



ANNEX B – Incident reporting policy risk matrix

Risk Matrix

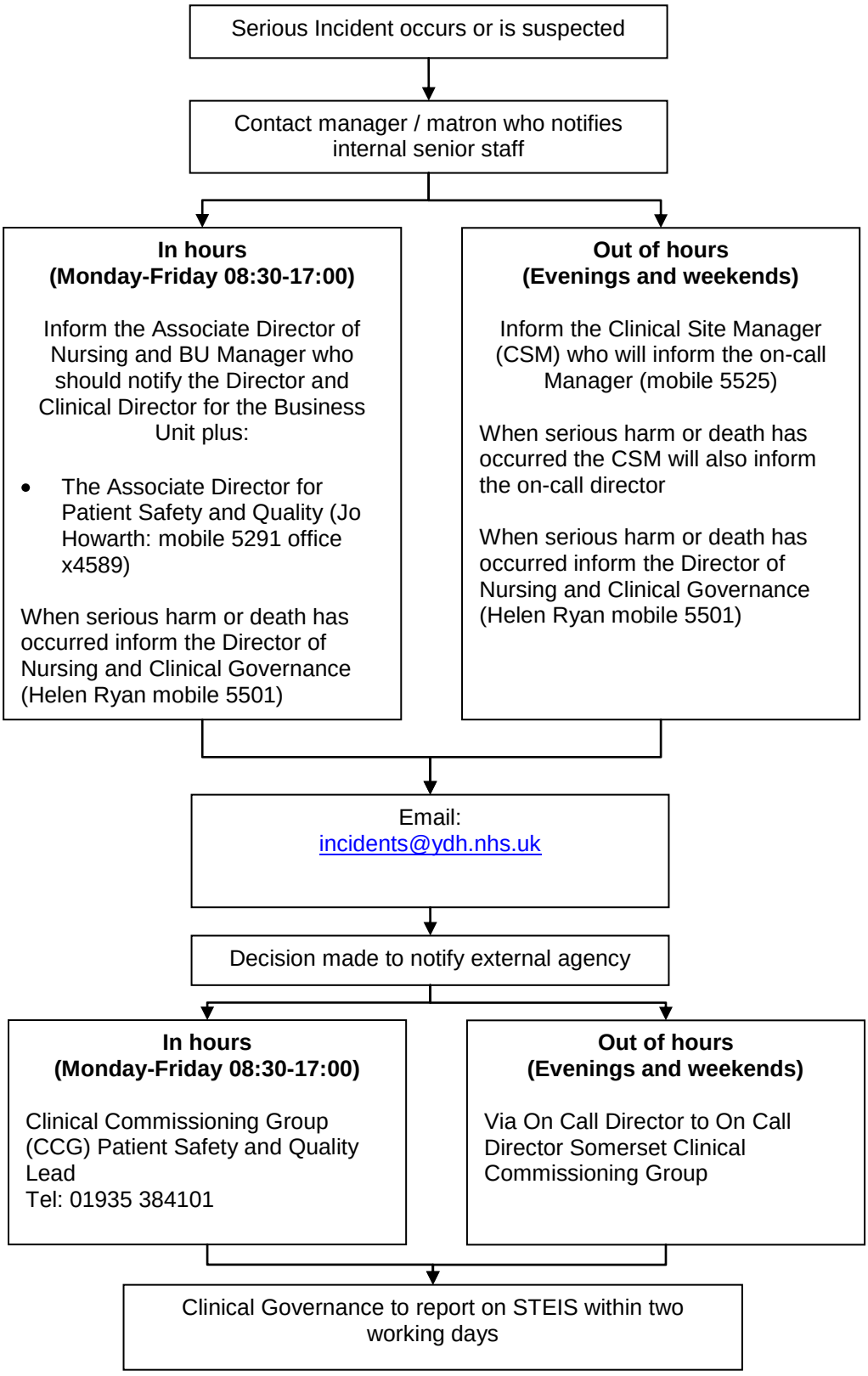
Consequence	Likelihood				
	Rare 1	**Unlikely 2**	**Possible 3**	**Likely 4**	**Certain 5**
Minor - 1	1	2	3	4	5
Moderate - 2	2	4	6	8	10
Significant or Major - 3	3	6	9	12	15
Fatality/Very High- 4	4	8	12	16	20
Multiple Fatalities - 5	5	10	15	20	25

KEY: Low risk | Moderate risk | Significant risk | High risk

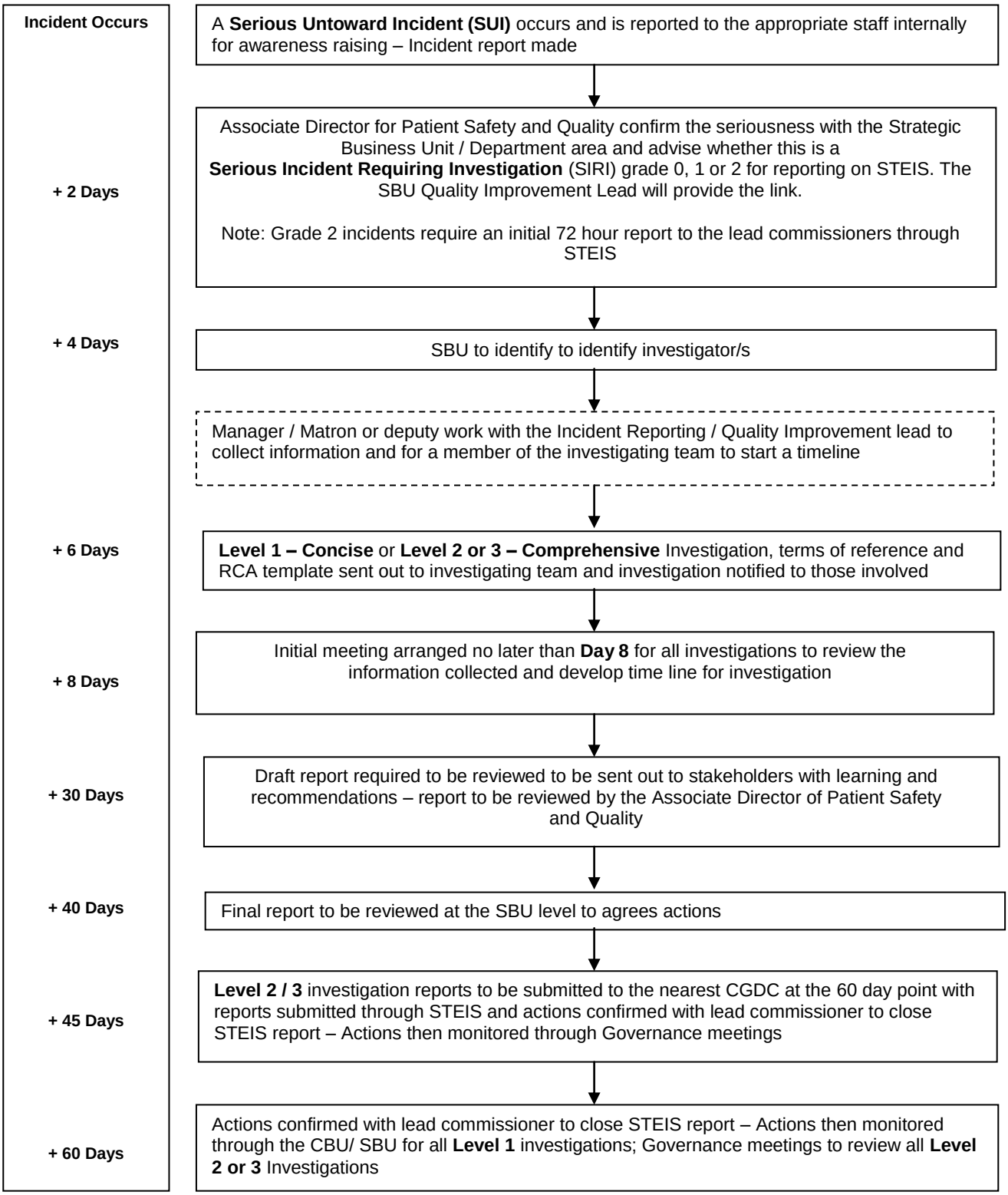
For grading risk, the scores obtained from the risk matrix are assigned grades as follows:

1-3 = Low Risk
4-6 = Moderate Risk
8-12 = Significant Risk
15-25 = High Risk

ANNEX C – Notification process for reporting serious incidents



ANNEX D – Timeline for Reporting and Investigating Incidents



ANNEX E – Regulation 20: Duty of Candour

Must act in an open and transparent way with relevant persons* in relation to care and treatment provided

1. As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred the Trust must:

a. notify the relevant person that the incident has occurred; and

b. provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

↓

2. The notification must:

a. be given in person by one or more representatives of the Trust;

b. provide an account, which to the best of the Trust's knowledge is true, of all the facts the Trust knows about the incident as at the date of the notification;

c. advise the relevant person what further enquiries into the incident the health service body believes are appropriate;

d. include an apology; and

e. be recorded in a written record securely kept by the Trust.

↓

3. The notification must be followed by a written notification given or sent to the relevant person containing:

a. the information provided under 2b;

b. details of any enquiries to be undertaken in accordance with 2c;

c. the results of any further enquiries into the incident; and

d. an apology.

↓

4. But if the relevant person cannot be contacted in person, or declines to speak to the Trust representative:

a. above boxes 1 to 3 are not to apply; and

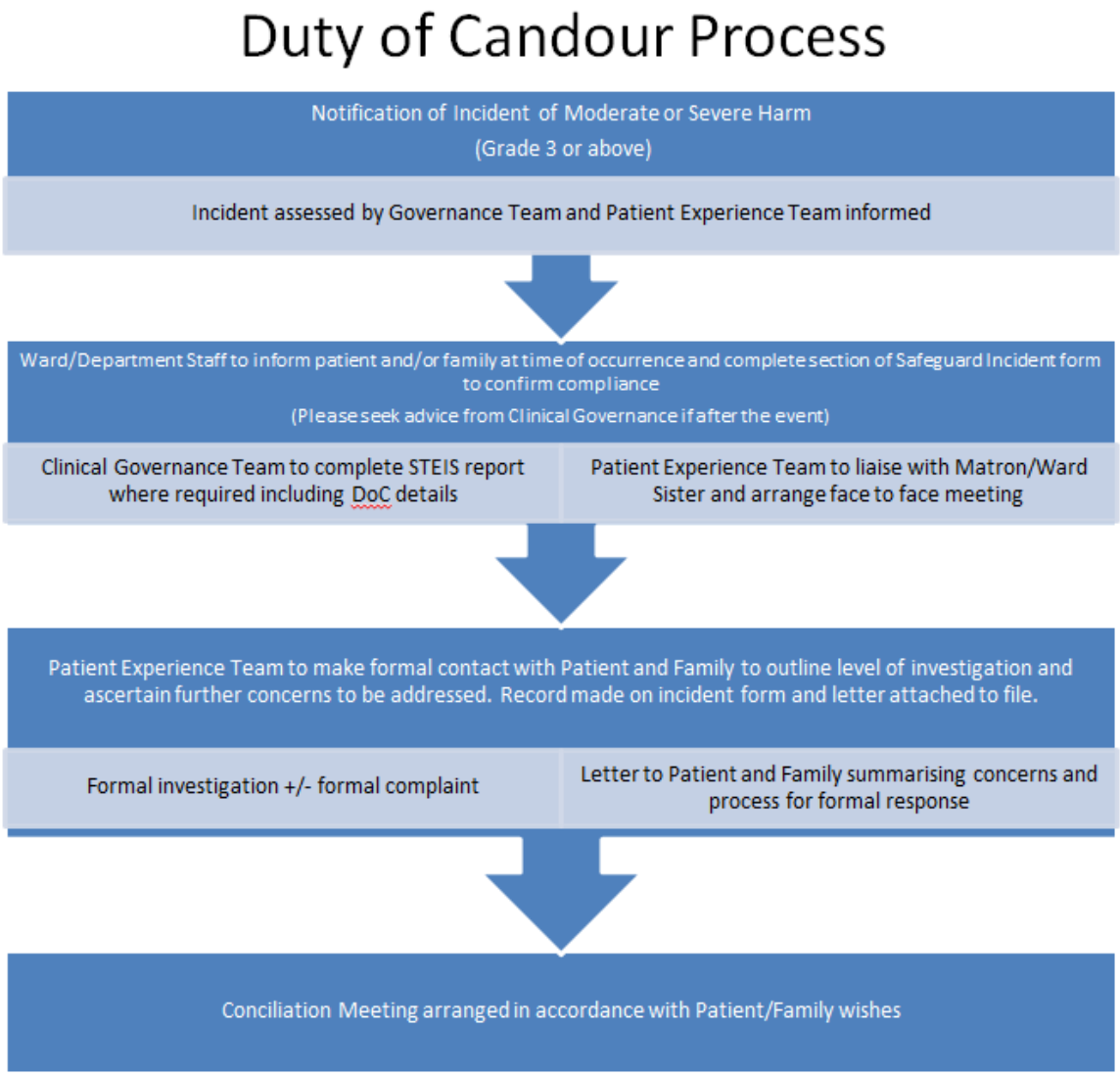
b. a written record is to be kept of attempts to contact or to speak to the relevant person

↓

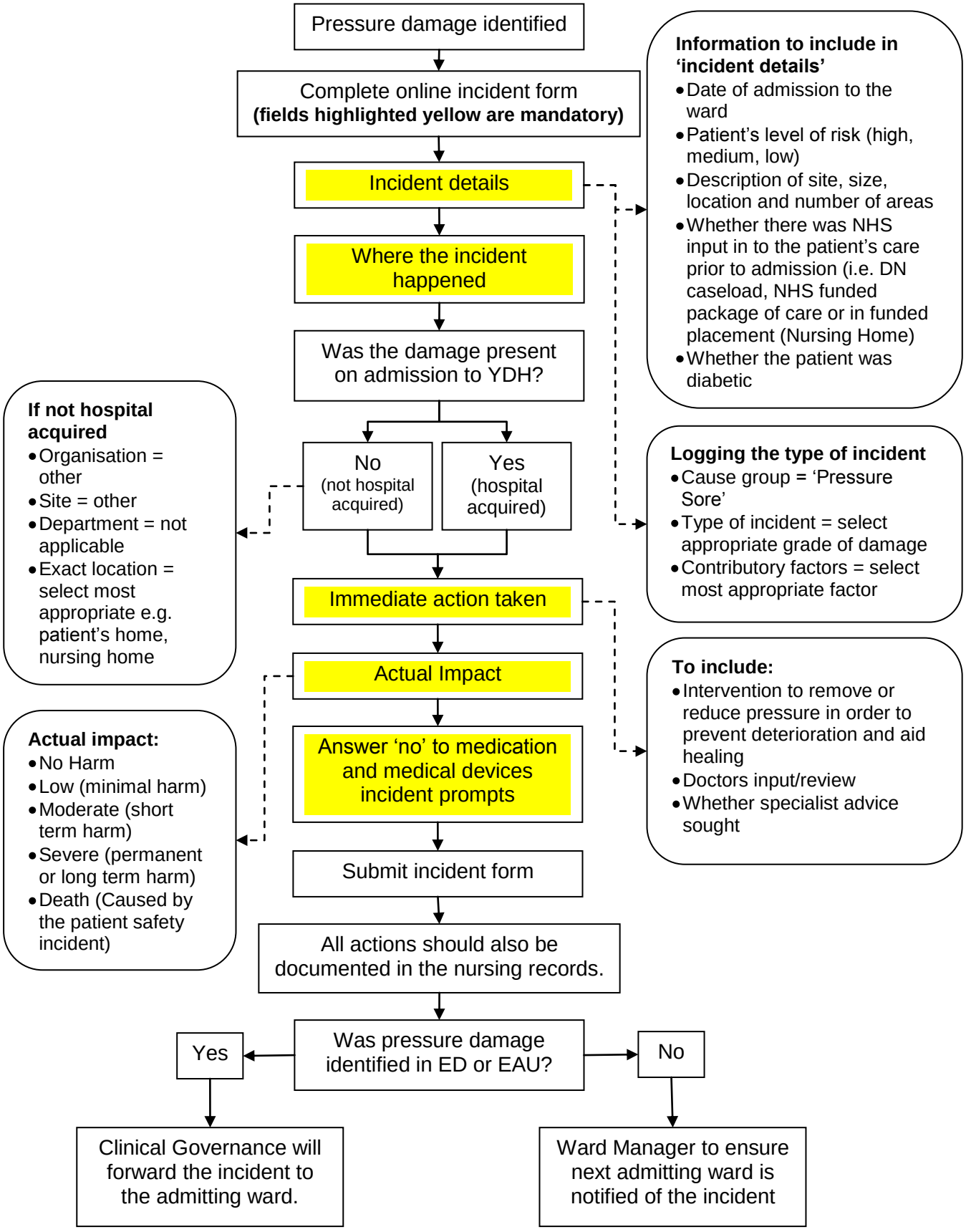
5. The Trust must keep a copy of all correspondence with the relevant person under box 3

*The relevant person is the person using the service and, in certain situations, extends to people acting lawfully on their behalf (for example a person under 16 who is not competent to make decisions about their care and treatment, or a person aged 16 or over who lacks the capacity to make decisions about their care and treatment). For those patients that are over the age of 16, and have capacity, staff should only speak to family members if the patient has given their permission for this.

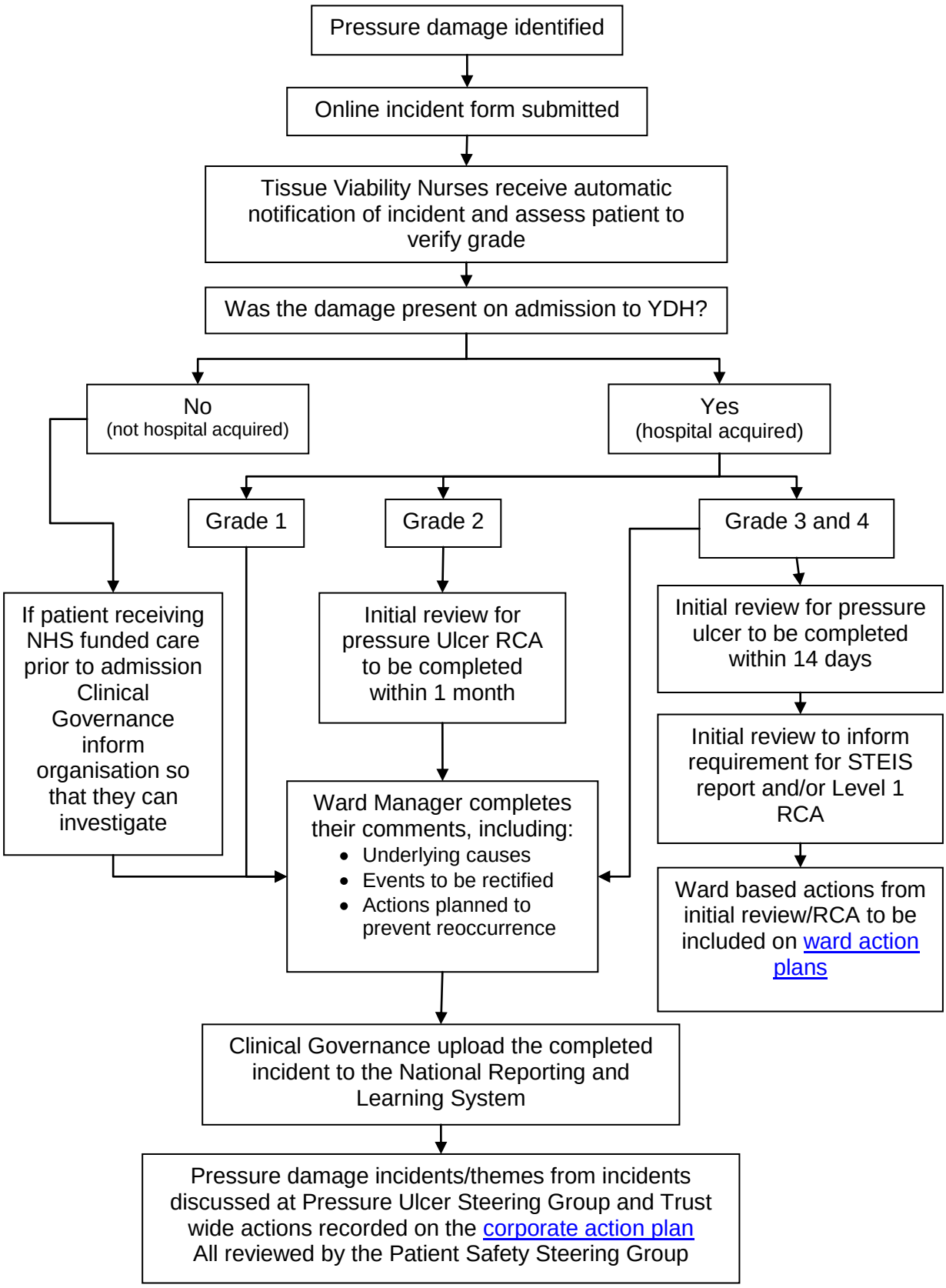
ANNEX F – Duty of Candour Process



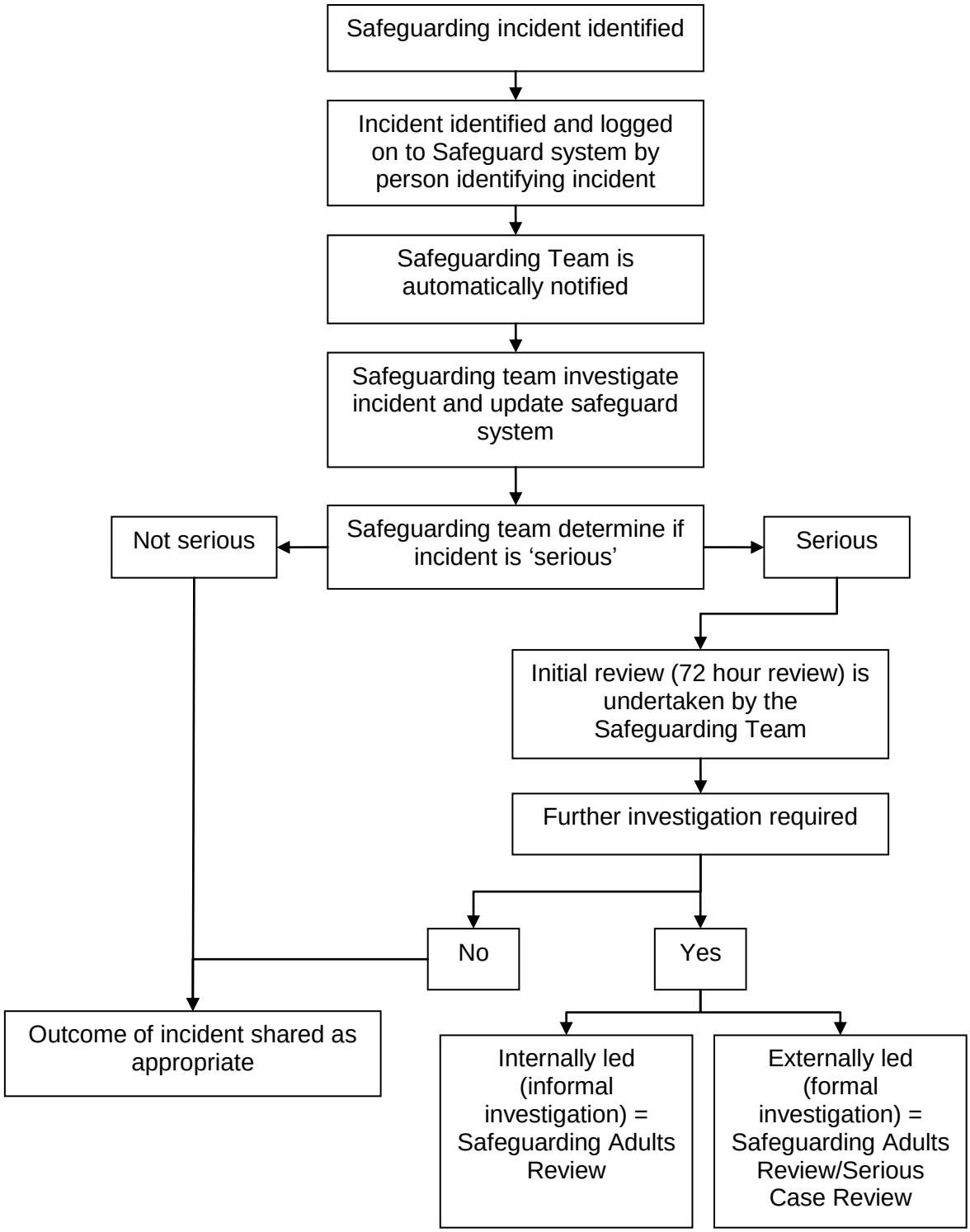
ANNEX G– Process for incident reporting pressure damage



ANNEX H – Process for investigating pressure damage



ANNEX I – Process for investigating safeguarding incidents



ANNEX J – Equality impact assessment tool

		Yes / No / N/A	Comments
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	Race	No	
	Ethnic origins (including gypsies and travellers)	No	
	Nationality	No	
	Gender	No	
	Culture	No	
	Religion or belief	No	
	Sexual orientation including lesbian, gay and bisexual people	No	
	Age	No	
	Disability	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	N/A	
4.	Is the impact of the policy/guidance likely to be negative?	No	
5.	If so can the impact be avoided?	N/A	
6.	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

For advice or if you have identified a potential discriminatory impact of this procedural document, please refer it to The Equality and Diversity Lead, together with any suggestions as to the action required to avoid/reduce this impact.

Signed: Jo Howarth Date: 14 July 2015

APPENDIX 1 – NHS England's overview of the serious incident management process

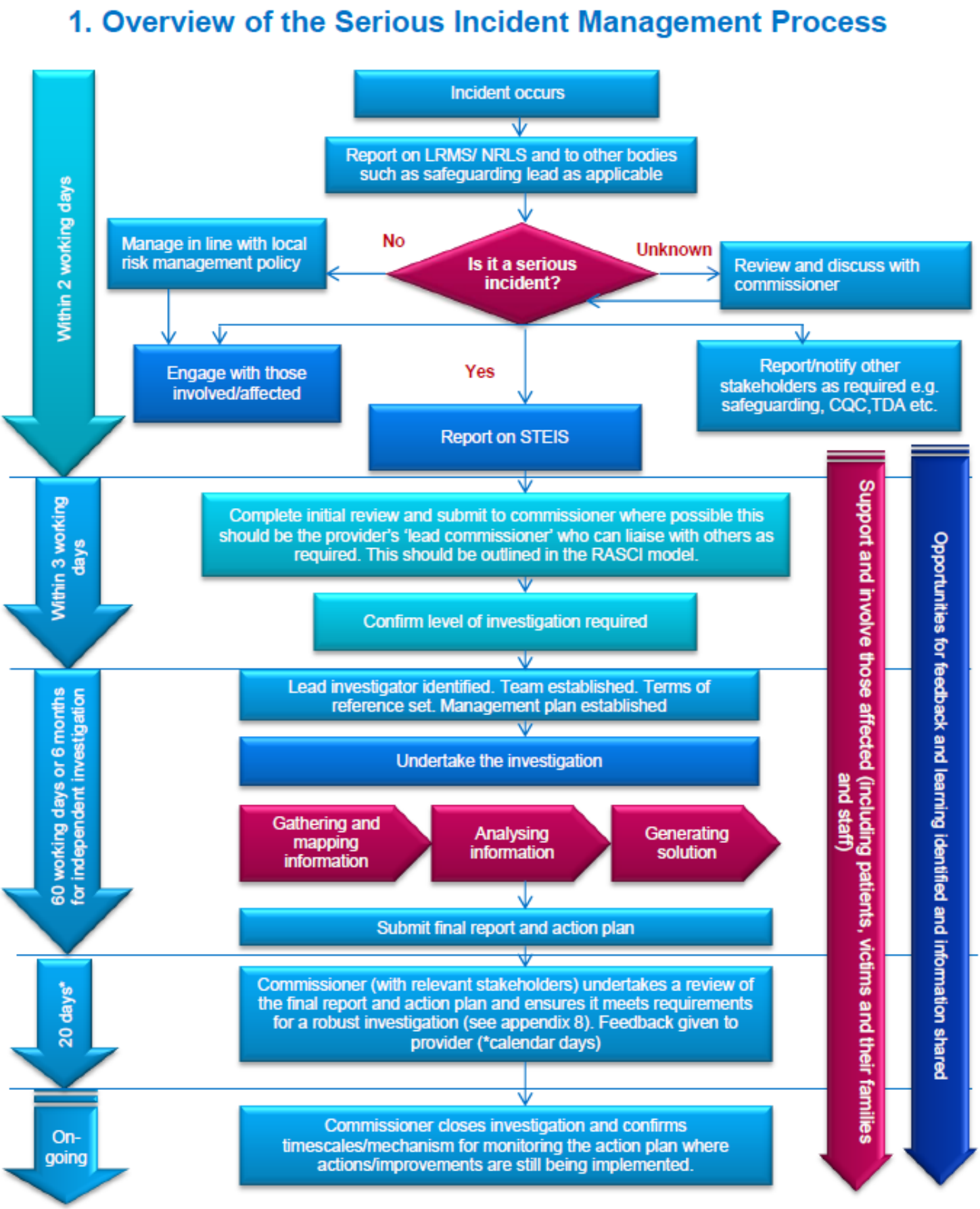


Figure 1: NHS England, Serious Incident Framework March 2015

APPENDIX 2 – NPSA Incident decision tree

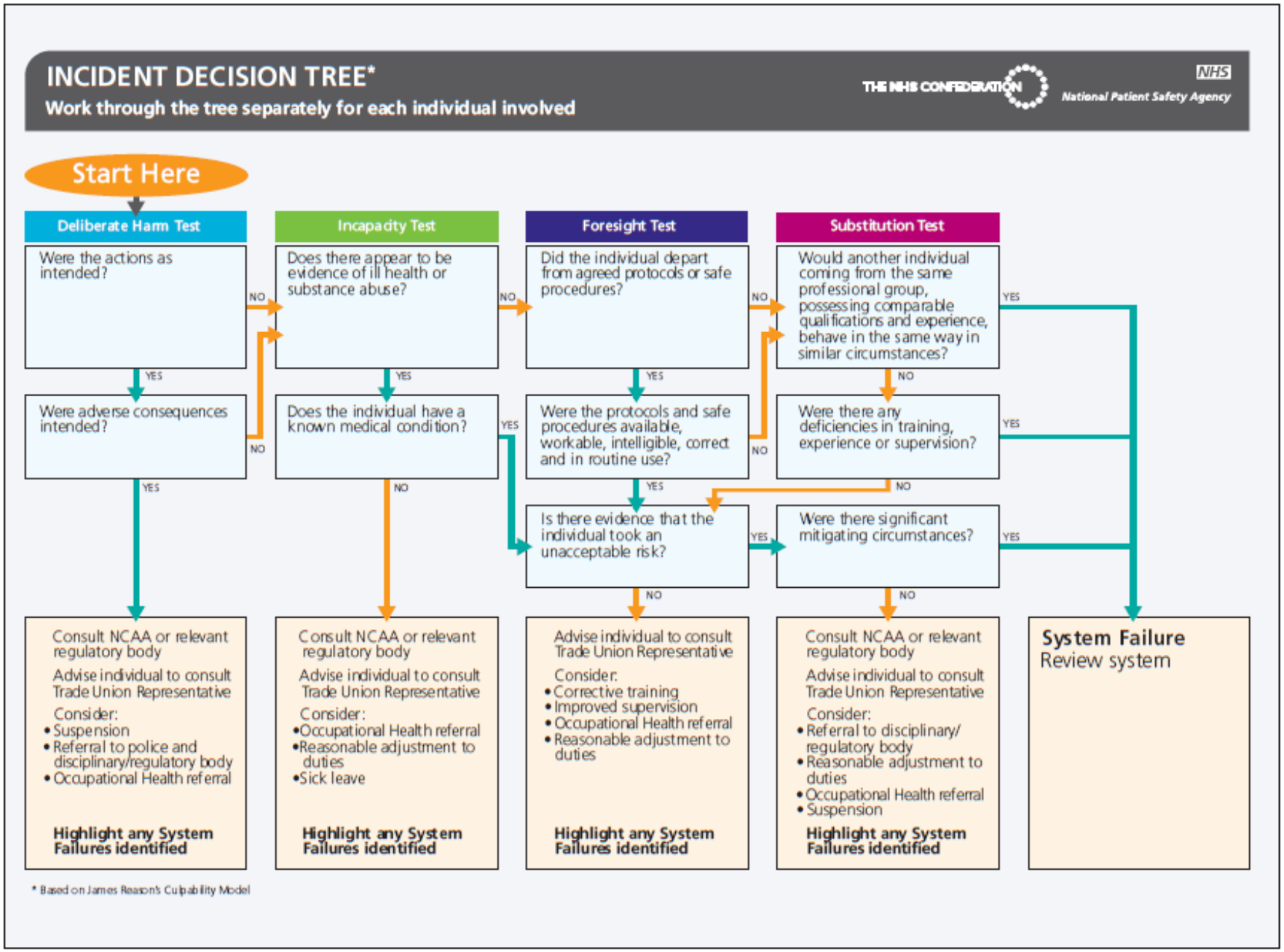


Figure 2: National Patient Safety Agency 2003, The Incident Decision Tree Information and advice on use